International Bureau

INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification 5 : A61B 17/36	A1	(11) International Publication Number: WO 93/21844 (43) International Publication Date: 11 November 1993 (11.11.93)

(21) International Application Number: PCT/US93/03849

(22) International Filing Date: 23 April 1993 (23.04.93)

(30) Priority data:
07/873,955 23 April 1992 (23.04.92) US

(71) Applicant: SCIMED LIFE SYSTEMS, INC. [US/US]; 6655 Wedgwood Road, Maple Grove, MN 55369 (US).

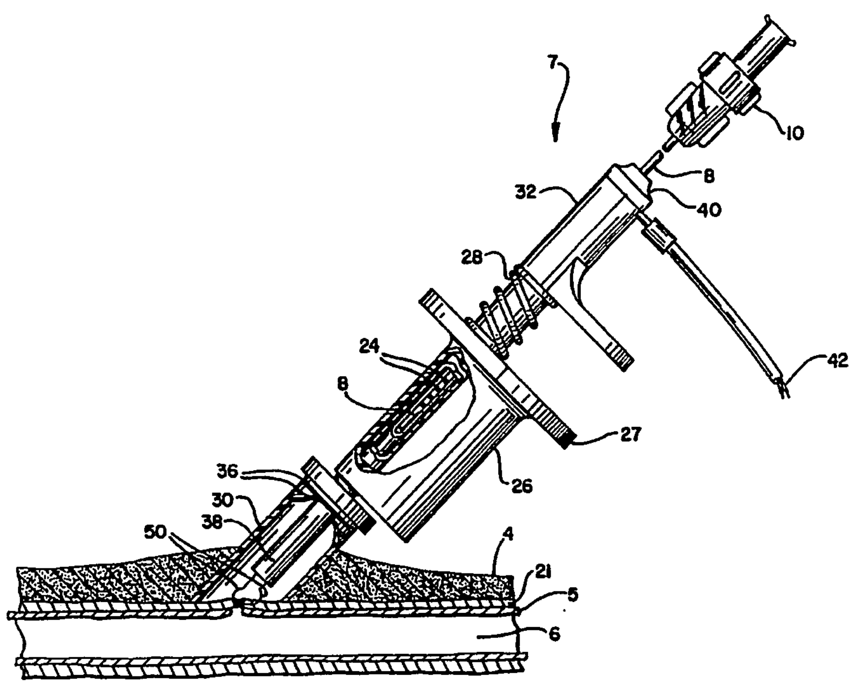
(72) Inventors: TAY, Sew, Wah ; 18555, 37th Avenue North, Plymouth, MN 55446 (US). SCHANKERILI, Kemal ; 7979 Neal Avenue North, Stillwater, MN 55082 (US). HOLMAN, Thomas ; 5621 Thomas Avenue South, Minneapolis, MN 55410 (US). MISCHE, Hans ; 1770 7th Street, South, St. Cloud, MN 56301 (US).

(74) Agent: SHURTZ, Steven, P.; Willian, Brinks, Olds, Hofer, Gilson & Lione, NBC Tower, Suite 3600, 455 North Cityfront Plaza Drive, Chicago, IL 60611 (US).

(81) Designated States: CA, JP, European patent (AT, BE, CH, DE, DK, ES, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE).

Published
With international search report.

(54) Title: APPARATUS AND METHOD FOR SEALING VASCULAR PUNCTURES



(57) Abstract

An apparatus (7) for closing and sealing a vascular puncture is connected to an energy supply such that heat is generated in, or thermally conducted to, the tissue, thereby thermally fusing the vascular tissue together. The method for closing and sealing a vascular puncture comprises applying radio frequency or other energy to the tissue, the energy being sufficient to thermally fuse the tissue together, thus sealing the puncture.

FOR THE PURPOSES OF INFORMATION ONLY

Codes used to identify States party to the PCT on the front pages of pamphlets publishing international applications under the PCT.

AT	Austria	FR	France	MR	Mauritania
AU	Australia	GA	Gabon	MW	Malawi
BB	Barbados	GB	United Kingdom	NL	Netherlands
BE	Belgium	GN	Guinea	NO	Norway
BF	Burkina Faso	GR	Greece	NZ	New Zealand
BG	Bulgaria	HU	Hungary	PL	Poland
BJ	Benin	IE	Ireland	PT	Portugal
BR	Brazil	IT	Italy	RO	Romania
CA	Canada	JP	Japan	RU	Russian Federation
CF	Central African Republic	KP	Democratic People's Republic of Korea	SD	Sudan
CG	Congo			SE	Sweden
CH	Switzerland	KR	Republic of Korea	SK	Slovak Republic
CI	Côte d'Ivoire	KZ	Kazakhstan	SN	Senegal
CM	Cameroon	LI	Liechtenstein	SU	Soviet Union
CS	Czechoslovakia	LK	Sri Lanka	TD	Chad
CZ	Czech Republic	LU	Luxembourg	TG	Togo
DE	Germany	MC	Monaco	UA	Ukraine
DK	Denmark	MG	Madagascar	US	United States of America
ES	Spain	ML	Mali	VN	Viet Nam
FI	Finland	MN	Mongolia		

APPARATUS AND METHOD FOR SEALING VASCULAR PUNCTURES

FIELD OF THE INVENTION

The present invention relates to an apparatus and method for closing and sealing vascular punctures. More particularly, the present invention relates to a novel apparatus and method for sealing a vascular puncture resulting from the use of a medical device, catheter system or the like by using radio frequency or other energy to effect closure and thermal fusing of a puncture.

BACKGROUND OF THE INVENTION

Many medical procedures require access into the vascular system of the patient. Although various means may be used to obtain access into a vein or artery, typically access is obtained by inserting a cannula or introducer sheath through the skin and into the selected blood vessel. A medical device or diagnostic instrument, such as a guide wire, guiding catheter, balloon angioplasty device, atherectomy device, or the like is then inserted into the vascular system through the cannula or introducer sheath.

In percutaneous transluminal coronary angioplasty, for example, it is customary to introduce a catheter into the femoral artery at an entry site in a patient's leg and to advance the catheter through the artery to the coronary region. The artery, which may be located

one half inch or more beneath the skin, is punctured with a needle or similar device. A guide wire is inserted through the needle and the needle is removed. An introducer sheath and dilator together are threaded over the guide wire. The introducer sheath is often twisted and otherwise manipulated as it is inserted into the vessel, thereby causing further enlargement of the vascular puncture. The dilator is then removed and the catheter is inserted.

To permit the insertion of a medical device or instrument therethrough, the introducer sheath must be of a relatively large diameter. Introducer sheaths typically have a diameter in the range between one millimeter and six millimeters, thus creating a significant puncture in the artery. After the intravascular medical procedure is completed, this puncture must be closed and bleeding from the blood vessel stopped.

At present, such bleeding is stopped by the application of direct digital pressure over the puncture site by a trained physician or other suitably trained medical personnel. Such direct pressure must be applied for a sufficiently long time for hemostasis to occur so that the opening is effectively closed and further bleeding is prevented. In the case of punctures into the femoral artery, the pressure is generally applied for twenty to thirty minutes, but it may be necessary to apply pressure for as long as one hour. Further, twelve pound sandbags may then be placed on the puncture site for an additional two to six hours.

The time required to stop bleeding using digital pressure is not an efficient use of medical professional services. Not only is this direct digital pressure application procedure wasteful of time by highly skilled medical professionals, the procedure results in a substantial reduction, if not virtual

arrest, of blood flow through the vessel. Since thrombosis is one of the major problems that can occur in the immediate post-operative period, any reduction in blood flow, caused by the application of digital pressure, is undesirable. Furthermore, when digital pressure is applied, an undesirable bruise or hematoma can form at the entry site, since internal bleeding of the punctured artery continues until clotting blocks the puncture. There is also a significant chance that upon movement by the patient, the puncture will reopen and begin bleeding again, resulting in a hematoma or other complications. In addition, when anticoagulants used in the medical procedure are left active in the body, the introducer sheath is generally left inside the patient for twelve to twenty four hours in order for the anticoagulants to clear from the blood. Because the patient may be required to remain immobile and because of the risk of complications, patients are usually required to remain overnight in the hospital for observation, thus greatly increasing the cost of the overall procedure.

One prior device for stopping bleeding from a puncture in a blood vessel is a type of expandable plug. An example of such a device is shown in U.S. Patent 4,890,612 (Kensey). The plug is pushed through the puncture into the blood vessel and into the blood stream. Once exposed to blood, it expands. The expanded plug is then pulled back against the puncture where, because of its expanded size, it plugs the opening. A similar device is an expandable closure, such as that described in U.S. Patent 4,852,568 (Kensey). Such devices may work satisfactorily, but require inserting and leaving a foreign object in the vessel for a period of time. It is usually medically preferable to avoid leaving objects in a vessel, even if they eventually biodegrade.

Another device for stopping bleeding from a puncture is disclosed in U.S. Patent 4,929,246 (Sinofsky). This patent relates to a method for closing an artery using laser energy while simultaneously applying pressure directly to the artery through the use of a balloon placed on the exterior of the artery over the puncture site.

SUMMARY OF THE INVENTION

An apparatus for closing and sealing a puncture at a puncture site in a vessel located beneath the skin using radio frequency or other energy to cauterize the puncture has been developed. In one aspect, the invention constitutes a probe sized to be percutaneously inserted adjacent the vascular opening and a connector for connecting the probe to an energy supply source; the probe being configured to conduct energy directly to tissue adjacent the probe to cause heating of tissue surrounding the vascular opening to close the opening.

In another aspect, the apparatus comprises a cautery device having a means for forcing together biological tissue surrounding a percutaneous vascular puncture and at least one electrode connectable to a radio frequency power source such that an electrical current may flow through the tissue, thermally fusing the tissue together.

In yet another aspect, the invention is an apparatus for the percutaneous medical treatment of biological tissue, comprising a plurality of electrodes connectable to a radio frequency power source, the electrodes adapted to engage biological tissue at spaced points; and a lumen connected to the electrodes for guiding the electrodes to the biological tissue at said spaced points.

In one specifically disclosed embodiment, the apparatus comprises a radio frequency cautery device

having forceps adapted to grasp vascular tissue surrounding the puncture site. The forceps, when connected to a radio frequency power source, also serve as bipolar electrodes for fusing the tissue surrounding the puncture.

A backstop element, such as a balloon occluder assembly or a T-shaped occluder, may also be used in conjunction with the cautery device. The balloon occluder assembly essentially comprises a balloon at the distal end of a balloon shaft and a means for inflating the balloon. The balloon occluder assembly temporarily occludes the puncture while providing a backstop against which the forceps may grasp the vascular tissue. The balloon occluder assembly also has utility separate from its use with the disclosed cautery device, as discussed more fully hereafter.

In another aspect, the invention is a method of sealing a vascular opening comprising the step of delivering energy to the vascular wall, resulting in local heating of bodily material external to the intima layer of the vessel to achieve hemostasis without substantially heating the intima layer of the vessel.

In yet another aspect, the method of the invention comprises the steps of percutaneously inserting a probe adjacent to the vascular opening; conducting energy from the probe directly to tissue adjacent the probe in an amount sufficient to cauterize the tissue to thereby close the vascular opening; and removing the probe.

The invention in still another aspect is a method of sealing a vascular puncture comprising the steps of holding the vascular tissue surrounding the puncture site in a contacting position and applying energy to that tissue, the energy being sufficient to thermally fuse the tissue together, thus sealing the puncture. Preferably, this method of sealing a puncture includes the steps of advancing a balloon into the lumen of a vessel, inflating the balloon and withdrawing it to

abut the puncture from within the vessel, inserting a cautery device having forceps connected to a radio frequency power source, grasping and bringing the vascular tissue into a contacting position, causing an electrical current to flow from one forceps, through the vascular tissue to the other forceps, thus effecting a closure by thermally fusing the vascular tissue together.

In another aspect of the invention, a balloon occluder need not be used. Instead, pressure is applied to the vessel to restrict blood flow therethrough, an electrode is percutaneously inserted to a position proximate the puncture site, and radio frequency energy is used to cause thrombosis of the blood to seal the puncture site.

The present invention thus provides an apparatus which is simple to use and which overcomes the disadvantages of the prior art, including the need for the application of digital pressure for long periods of time and the possibility of a substantial reduction of blood flow through the vessel. The present invention also provides methods that are effective for closing off a puncture or other opening in a blood vessel by using radio frequency or other energy to thermally fuse the vascular tissue or form a seal by causing thrombosis of the blood. The puncture is hemostatically sealed almost immediately after the medical procedure is performed, thus avoiding any potential complications associated with re-opening of the puncture or long hospital stays while anticoagulants remain active in the body.

The forgoing has outlined rather broadly the advantages of the present invention. Additional benefits of the invention will be described hereinafter. These advantages, as well as the invention itself, are more easily understood in view of the

attached drawings, a brief description of which follows.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is an exploded view of the first preferred apparatus embodiment of the present invention.

FIG. 2 is an enlarged cross-sectional view of the distal portion of the device of the first preferred embodiment.

FIG. 3 is an enlarged perspective view of the distal end of a forceps of the first preferred embodiment.

FIG. 4 is an enlarged cross-sectional view of the distal end of a forceps of the first preferred embodiment.

FIG. 5 is an enlarged cross-sectional view of a check valve assembly and hub used in conjunction with the inflation means of the first preferred embodiment.

FIG. 6 through FIG. 8 illustrate alternate embodiments of the actuating mechanism.

FIG. 9 through FIG. 18 are partial cross-sectional views illustrating the method of using the first preferred embodiment of the present invention.

FIG. 9A is a partial cross-sectional view taken along line 9A-9A of FIG. 9 showing the relationship of the arterial sheath to the femoral artery and associated anatomy.

FIG. 15A is an enlarged cross-sectional view of the region of FIG. 15 showing the various layers of the vascular tissue being contacted by the electrodes.

FIG. 17A is an enlarged cross-sectional view of the region of FIG. 17 where the seal is made.

FIG. 19A and 19B illustrate an alternate embodiment of the backstop element of the present invention.

DETAILED DESCRIPTION OF THE DRAWINGS AND PREFERRED EMBODIMENTS OF THE INVENTION

Before describing the apparatus of the present invention, a brief description of a typical intravascular surgical procedure, e.g., catheter instrumentation of an artery using a percutaneous incision or puncture, will be given to best appreciate the features of the cautery apparatus of the present invention. In such a procedure a cannula of an instrument, such as an angiographic needle, is inserted percutaneously through the skin and arterial sheath and into the artery. The needle cannula of an instrument is held in place and the flexible end of a guide wire is then passed through the cannula into the artery to the desired depth (i.e., longitudinal position therealong). Once the guidewire is in place the needle cannula is removed leaving the guidewire in place. A conventional introducer sheath combined with an arterial dilator are then passed over the guidewire through the puncture and into the artery. The guidewire and the dilator are then removed leaving the sheath in place. The catheter is then inserted through the introducer sheath and threaded down the artery to the desired intravascular location, e.g., the situs of the atherosclerotic occlusion, usually the coronary region. Once the intravascular procedure has been completed, the catheter is removed. Thereafter, once anticoagulants have been inactivated or cleared from the body, the usual procedure has been to remove the sheath and to have a surgeon or other trained person apply digital pressure to the percutaneous puncture until hemostasis has occurred. As noted above, the stopping of bleeding from a puncture was previously a difficult and time consuming task.

The apparatus of the present invention effects the hemostatic closure of a percutaneous or other type of puncture, incision or opening in a body vessel without necessitating the application of digital pressure

thereto. In accordance with the preferred embodiment of the present invention, the introducer sheath is left in place after the catheter is removed and a balloon occluder is advanced through the introducer sheath into the vessel lumen. In additional preferred embodiments, any backstop element, such as a T-shaped occluder, can be used to support the tissue surrounding the puncture. A cautery device having forceps which are connected to a radio frequency power source are then inserted into the skin to the puncture site, where the forceps grasp the vascular tissue surrounding the puncture. The balloon or T-shaped occluder is withdrawn and the device is then energized, causing a cauterizing discharge to pass from the device to the vascular tissue surrounding the puncture, thereby thermally fusing the puncture.

Referring now in greater detail to the various figures of the drawing wherein like reference characters refer to like parts, FIG. 1 generally illustrates a cautery apparatus of the first preferred embodiment. This apparatus consists essentially of three components: a cautery device 7, a balloon occluder assembly 15 and a radio frequency power source (not shown). The apparatus functions to close and seal a puncture or other opening in a blood vessel, duct or lumen in a living being. The apparatus thus has particular utility when used in connection with intravascular procedures such as angioplasty and other types of recanalization of atherosclerotic arteries, etc. However, it should be appreciated that the apparatus can be used to hemostatically close a puncture or other opening within a body. Thus, it is to be understood that while the description of the invention contained herein is directed to closing and sealing percutaneous punctures in vessels, the apparatus has other applications.

The cautery device or probe 7 of the first preferred embodiment comprises a gripping handle 26, a tubular retaining housing 38, a spring 28, a thumb rest 32, forceps 50, a cap 40, an inner tubular housing 41 and detachable electrical leads 42. The gripping handle 26 is preferably cylindrical, but may be of any shape or size which allows it to be conveniently grasped with one hand. The gripping handle 26, for example, may incorporate an outwardly projecting annular ledge 27 or any other additional element which allows it to be easily grasped and held. The gripping handle 26, as well as the cap 40 and the thumb rest 32, can be constructed from any suitable material, preferably a lightweight plastic, such as polycarbonate or acrylonitrile-butadiene-styrene copolymer (ABS). The cap 40 is located at the proximal end of the thumb rest 32 and provides outlets for the balloon shaft 8 and the detachable electrical leads 42.

In the first preferred embodiment, the thumb rest 32, the spring 28 and the gripping handle 26 comprise the actuator element. While holding the gripping handle 26, the thumb rest 32 is used to oppose the spring force of the spring 28, actuating the forceps 50. Actuating the forceps 50 causes the forceps to move from a first stored position to a second open position, as discussed more fully hereafter.

The tubular retaining housing 38, the distal end of which is also referred to as an elongated cautery probe or a cautery probe tip, is preferably an elongated, thin-walled tube or lumen made of any common plastic, including but not limited to PTFE, polyethylene, polyurethane, polycarbonate, polyester, nylon or ABS. The wall of the housing 38 is preferably 0.010" thick, but may be between 0.005" and 0.030". The inner diameter of the housing 38 is preferably about 0.158" and may vary from approximately 0.010" to 0.250". The tubular retaining housing 38 has an inner

tubular housing 41 inside, which provides a guide lumen. The inner tubular housing 41, along with the tubular retaining housing 38, are used to guide the forceps 50 to the puncture site.

Detachable electrical leads 42 connect the proximal end of the forceps 50 to the power source, allowing the forceps 50 to act as electrodes. Any connector element, however, that connects the forceps to the power supply is contemplated by the present invention. Further, the connector element may also include an activating switch element, such as a thumb switch, which allows the electrical current to flow only when said switch element is activated. Alternatively, a foot switch associated with the power source may be used. The activating switch element may also include a timing feature which allows the physician to energize the device for a predetermined amount of time, regardless of how long the switch element is engaged.

In their first position, the forceps 50 reside substantially inside the tubular retaining housing 38 (FIG. 2). The forceps 50 are insulated, preferably with plastic insulation 51, except for the distal end where the gripping of tissue occurs (FIG. 4). Any suitable insulating material may also be used. The distal end of the forceps 50 of the first preferred embodiment form an arc of approximately 160° and have a serrated gripping portion 52 (FIG.3). The forceps are preferably up to 2 mm wide at their gripping portion 52. The gripping portion 52 of the forceps 50 will preferably almost touch when just outside the distal end of the tubular retaining housing 38. When in use, the vascular tissue is disposed in this gap. The forceps 50 are preferably uneven in length to accommodate the angle of entry of the cautery device 7 into the skin (as shown in FIG. 14), the angle ideally being 45° to the surface of the vessel. For additional

preferred embodiments, the forceps are preformed into any shape that is advantageous for gripping tissue and may be of even or uneven length. The forceps 50 are preferably made of a metal alloy such as Elgiloy™, manufactured by Elgiloy Partnership, Ltd., MP-35N™ or hardened stainless steel, but may be made of any material suitable for the purpose of gripping biological tissue.

Preferably, the forceps comprise bipolar electrodes. Thus, at any one time, one forceps will function as the anode and the other as the cathode. Although the first preferred embodiment contemplates the use of only two forceps, embodiments including a plurality of forceps are also contemplated. In these embodiments, the firing or activating of the current can be controlled electronically to occur in sequence.

As best shown in FIGS. 1 and 2, the inner tubular housing 41, also referred to as a guide lumen, is a thin tube preferably made of any common plastic, including but not limited to PTFE, polyethylene, polyurethane, polycarbonate, polyester, nylon or ABS. It is located between the substantially parallel arm portions of the insulated forceps 50 and extends through the gripping handle 26 and the tubular retaining housing 38. The inner tubular housing 41 allows the balloon shaft 8 of the balloon occluder assembly 15 to pass through the forceps 50 and out through the proximal end of the cautery device 7. In additional preferred embodiments, conventional triple lumen tubing comprising an inner hollow tube connected to the inside of an outer hollow tube by two longitudinally extending flat sections can be used in place of the combination of the tubular retaining housing 38 and the inner tubular housing 41. The triple lumen tubing is advantageous in that it isolates the forceps from each other and from the balloon shaft and avoids the need for constructing the tubular retaining housing

38 and the inner tubular housing 41 from separate elements.

The balloon occluder assembly 15 of the first preferred embodiment consists of a elongated balloon shaft 8 having spaced markings 24 on the distal portion thereof, a balloon 14 at the distal end of shaft 8, a check valve assembly 20 on the proximal portion of the shaft 8, a removable hub 10 and a syringe 12.

The balloon shaft 8 is essentially a thin tube or lumen made of plastic or metal. The balloon shaft has an outer diameter of approximately 0.050" and an inner diameter of approximately 0.040". The balloon 14, disposed at the distal end of the balloon shaft 8, may be made with any suitable material including, but not limited to, latex, polyurethane, silicone, polyethylene terephthalate (PETP) and polyethylene copolymer, and may be compliant or non-compliant. Preferably, the balloon is made from a natural rubber latex material and is shaped in the form of a flat disk, though spherical and cylindrical forms are also acceptable. The balloon may be of any shape and size suitable to occlude the puncture being sealed. The balloon 14 may also be fitted with a balloon protector (not shown). The protector is a lumen or tube, made of plastic, PTFE, PETP or any other suitable material, which fits around the balloon 14 to protect the balloon from being torn or ripped and also, if necessary, to alter the shape of the inflated balloon by radially compressing certain areas of the balloon.

The check valve assembly 20 at the proximal end of balloon shaft 8 provides a means for inflating and keeping the balloon 14 inflated for the desired period of time. The diameter of both the balloon shaft 8 and the check valve assembly 20 is preferably smaller than approximately 0.12" (9 French), although both can be of any size which allows the cautery device to be easily inserted over them. As best seen in FIG. 5, the

preferred embodiment of the check valve assembly 20 consists essentially of housing 60 into which the proximal end of the balloon shaft 8 enters, an air passage 62 connecting the balloon shaft 8 to a chamber 64. The chamber 64 has a conical portion at the proximal end and a shelf 68 at the distal end thereof. The chamber also contains a spherical member 70, which is movable between a first and second position within the chamber 64. When in a first position (as shown in FIG. 5), the spherical member 70 is in a contacting position with the shelf 68, which prevents the spherical member 70 from blocking the air passage 62. The spherical member 70 is held in this position by the pin element 72, discussed below. Thus air is allowed to pass through the assembly to inflate or deflate the balloon 14. At a second position, the spherical member 70 lodges against the conical portion of the chamber 64, completely preventing any air from passing through the assembly. Also contemplated by this invention are other conventional check valve assemblies.

A removable hub 10 with a standard female luer fitting is adapted to attach to the check valve assembly 20. The hub 10 generally provides a means for deflating the balloon 14, and, in conjunction with a syringe 12, for inflating the balloon. In the first preferred embodiment, a pin element 72 in the hub 10 provides a means for moving the spherical member 70 of the check valve assembly 20 from a position where it blocks the flow of air through the assembly to a position where the flow of air is unimpeded. The hub 10 may be made from any suitable material, such as polycarbonate or high-density ABS, and may be of any shape and size suitable for accomplishing the desired task.

A syringe 12 attaches to the removable hub 10 via a standard female luer fitting on the proximal end of the hub 10 and provides a means for inflating the

balloon 14. Preferably, a 1 ml syringe is used. A liquid or a gas may be used to inflate the balloon 14, though a solution of saline is preferable.

A suitable radio frequency power source (not shown) is the Wet Field II made by Mentor O&O, Inc. The power source may be either alternating current (AC) or direct current (DC).

The cautery apparatus of the first preferred embodiment also includes other secondary components, such as a conventional introducer sheath 2, a dilator 34, a cautery sheath 30 and an introducer (not shown). The introducer sheath 2 comprises a hollow tube which extends into the vessel lumen 6 (FIG. 9). It is left in the artery after the catheterization or other percutaneous intravascular procedure and is standard and well known in the art. It is generally made from a suitable, flexible material, such as polyurethane, PTFE or polyethylene. Typical introducer sheaths range in diameter from 5 to 20 French and contain a diaphragm at the proximal end thereof to prevent the fluid in the lumen of the vessel from escaping through the sheath 2 once it is inserted into the vessel. Any suitably sized and constructed introducer sheath may be used.

The introducer (not shown), which is also conventional, is a small hollow tube having a tapered distal end. The introducer is adapted to be inserted into the proximal end of the introducer sheath 2. The introducer spreads apart the walls of the diaphragm in the introducer sheath 2 to allow a portion of an instrument, such as a guide wire, to be inserted into the introducer sheath without damaging the instrument. When used in practicing the method of the present invention, the introducer is used to allow insertion of the distal end of the balloon occluder assembly, which contains a relatively fragile balloon 14, into the introducer sheath and hence into the vessel lumen 6.

The cautery sheath 30 is similar to the introducer sheath 2, except that it is larger in diameter and not designed to extend into the vessel lumen 6 (FIG. 12). The cautery sheath 30 is a hollow tube which is adapted to be inserted into the skin after the introducer sheath 2 has been removed and around the balloon shaft 8 already in place. The cautery sheath 30 spreads and holds the skin and subcutaneous tissue above the vascular puncture away from the balloon shaft 8 and allows the tubular retaining housing 38 containing the forceps 50 to be inserted into the body without contacting the surface of the skin or any subdermal tissue. It may be made of any suitable material including polyethylene, polyurethane and PTFE and may have an inner diameter of approximately 0.10" to 0.250", but in any case, must be larger in diameter than the tubular retaining housing. The cautery sheath 30 of the first preferred embodiment is capable of spreading the tissue to an opening dimension that is both larger than the opening in the vessel wall and larger than the dimension of the portion of the energy delivery probe used to contact the tissue surrounding the opening. The cautery sheath 30 is also generally about 3"-4" in length. The distal end of the cautery sheath 30 is preferably cut at a 45° angle, but any suitable angle is also acceptable. The cautery sheath 30 has markings 36, which correspond to the markings 24 on the balloon shaft 8. These markings could be numbers or a sequence of color bands. Also contemplated are other marking systems where the physician is able to identify and locate the exact depth of the puncture.

The dilator 34 is a hollow tube portion having a blunted tapered distal end portion (FIG. 12). The tapered distal end is adapted to be inserted into the skin above the puncture site and over the balloon shaft 8 to gradually spread the skin apart. The tapered

distal end is blunted, however, so that it abuts the exterior surface of the vessel surrounding the puncture. The dilator 34 is generally longer than the cautery sheath 30 so that it may be conveniently removed from the cautery sheath. Prior to insertion into the skin, the dilator 34 is fitted inside the cautery sheath 30, with the blunted tapered distal end of the dilator extending beyond the distal end of the cautery sheath. In use, the distal end of the dilator 34 is inserted first, followed by the distal end of the cautery sheath 30. Once the cautery sheath 30 is in place, i.e., its distal end contacting the exterior surface of the vessel wall, the dilator 34 is removed (FIG. 12).

The cautery device 7, the balloon occluder assembly 15 and all the secondary components mentioned above may be disposed of after one use. The power supply, however, may be reused.

Generally, the present invention contemplates various methods of using radio frequency and other energy to seal a percutaneous vascular puncture. Operation of the first preferred embodiment of the cautery apparatus may be explained with reference to FIGS. 9 - 18.

FIG. 9A show the location of the vascular sheath 21 with respect to the vessel wall 5, in this case the femoral artery. The vascular sheath 21 is actually made of an outer layer 22 that comprises collagen, a fatty layer 23 and a thin connective tissue 25 in contact with the artery wall 5. At the point in the body where punctures are made for percutaneous transluminal coronary angioplasty procedures, the outer layer 22 of the arterial sheath 21 is actually a continuation of the iliac facia combined with the facia transversalis, which come together at the femoral triangle to form the sheath. The fatty layer 23 is a funnel shaped areolar tissue which encapsulates the

vascular bundle (the femoral artery 5, the femoral vein 9 and lymph canal 13). The fatty areolar tissue is made of clusters of fat cells linked together by collagenous connective fibers. As used herein and in the claims, the term vascular tissue includes the vessel wall and any associated vascular sheath. It has been found that the vascular sheath 21, as explained more fully below, plays a role in properly closing the puncture site in the vessel wall 5.

In use, a catheter introducer sheath 2, if not already in place from a prior medical procedure, is inserted into a vessel, such that it extends from the interior of the vessel lumen 6, through the vessel wall 5 and out through the vascular sheath 21, subcutaneous tissue and skin surface 4 of the patient (FIG. 9). The distal portion of the balloon occluder assembly 15 is inserted into the introducer sheath 2 through the diaphragm using the introducer (not shown), and pushed until the distal end of the balloon shaft 8 extends beyond the distal end of the introducer sheath 2 (FIG. 10).

The syringe 12 and the removable hub 10 are attached to the check valve assembly 20, and the balloon 14 is inflated with a predetermined volume of fluid, preferably saline. The balloon 14 is inflated to a size sufficient to occlude the puncture and preferably in the form of a sphere as shown, or more preferably in the form of a flat disk. Preferably, the syringe 12 is sized such that full displacement of its piston will provide the exact amount of fluid to properly inflate the balloon 14. The removable hub 10, together with the syringe 12, are then removed from the balloon occluder assembly 15. The check valve assembly 20 prevents deflation of the balloon.

The balloon 14 is withdrawn (i.e., pulled out of the body) until the inflated balloon abuts the distal end of the introducer sheath 2, and then both are

withdrawn until the balloon abuts the puncture. At this point, the introducer sheath 2 is totally removed from the body, exposing the color bands or marking 24 on the balloon shaft 8 (FIG. 11). The balloon 14 temporarily occludes the puncture site to prevent bleeding. Digital pressure is thus not required.

The physician notes the markings 24 on the shaft 8 at the point where the shaft meets the surface of the skin (FIG. 11). The balloon occluder assembly 15, in addition to temporarily occluding the puncture, also functions to (a) identify for the physician the exact depth of the puncture, (b) provide positioning support for the area surrounding the puncture so that the forceps 50 may more easily grasp the vascular tissue (i.e., a backstop element), (c) act as a guide for a hemostatic device, including, but not limited to the cautery device 7 of the present invention and (d) to keep the vascular tissue through which the puncture has been made separated from the tissue of the opposite vessel wall. The importance of the various functions of the balloon occluder assembly 15 will become more evident as the subsequent steps in the preferred method are explained. It will be understood that backstop elements of additional preferred embodiments will also perform some or all of these functions.

The cautery sheath 30 and dilator 34 are inserted over the shaft 8 of the balloon occluder assembly 15 and into the skin. Based on the depth markings, the tapered distal end of the dilator 34 and cautery sheath 30 are inserted so that they do not penetrate the vessel, but merely abut it (FIG. 12). Once the cautery sheath 30 is in place, the dilator 34 is removed.

Referring to FIG. 13, the cautery device 7 is inserted over the shaft 8 of the balloon occluder assembly 15 and into the cautery sheath 30. As can be seen in FIG. 13, the check valve assembly 20, located

at the proximal end of the shaft 8, is small enough in diameter to thread the cautery device 7 over it. The markings on the balloon shaft 8 and the cautery sheath 30 provide a means for placing the cautery device 7 at a predetermined distance from the puncture site.

The thumb rest 32 on the cautery device 7 is then depressed, causing the spring 28 to actuate the forceps 50 (FIG. 14). Upon actuation, the forceps 50 extend beyond the tubular retaining housing 38 and expand slightly due to the lack of radial compression provided by the retaining housing 38. The balloon occluder assembly is withdrawn slightly so as to bring the vascular tissue into proper position. The serrated gripping portion 52 of the forceps 50 grasps the vascular tissue surrounding the puncture at spaced points (FIG. 14). The balloon 14 provides, among other things, a backstop against which the vascular tissue is grasped. Referring to FIG. 15, the thumb rest 32 is released, causing the forceps 50 to retract or withdraw into the retaining housing 38, thus pulling the grasped tissue together until stopped by the balloon occluder assembly 15.

As shown in detail in FIG. 15A, the vessel wall 5 is made of three layers. The innermost layer is the intima 16, which is the most delicate and important layer for vessel health and healing. It is preferred that any heat conducted to or generated in the vessel wall be limited to the other layers so that the intima layer is not substantially heated so as to preserve the cells in the intima layer. The second layer is the media 17. The media is dense and will resist being pulled by the forceps 50. The outer layer is the adventitia 18. The adventitia is fibrous and somewhat loose. It is easier to grasp and is more flexible and elastic than the other layers. If the forceps 50 anchor in the adventitia layer 18, the adventitia can

be pulled closed without drawing the media layer 17 together.

Preferably the forceps 50 penetrate through the vascular sheath 21 and anchor in the adventitia layer 18 as shown in FIG. 15A. The balloon 14 is then deflated by putting the hub 10 back onto the end of the check valve assembly 20 (FIG. 16). The deflated balloon passes through the grasped tissue. The entire balloon occluder assembly 15 is fully withdrawn from the cautery device 7. The forceps 50 continue to grasp the tissue, pulling the vascular sheath 21 and adventitia layer 18 surrounding the puncture together (FIG. 16).

The radio frequency power supply (not shown) is then activated and the electrodes are energized. In the first preferred method, a thumb or foot switch is used to activate the power. The tissue in between the forceps 50, which serve as electrodes, acts as a high resistance conductor. It will be understood that the parameters of the electrical energy applied to the vascular tissue surrounding the puncture site must be selected to thermally fuse the puncture without causing widespread damage to the tissue or coagulating blood in the vessel. The frequency of the alternating electrical energy can be anywhere in the radio frequency range (10 kHz to 300 GHz). For medical reasons, the frequency should be above 25 kHz. For most applications, a high frequency energy range, generally 300 kHz to 1,000 kHz, may be used, with the frequency preferably being in the range of 300 kHz to 600 kHz, more preferably between 450 kHz and 550 kHz, and most preferably 500 kHz. In other applications, frequencies in the short wave range (10 MHz to 100 MHz), or in the microwave range (1 GHz to 300 GHz), will be more useful. A duration of application of the energy will generally be between about one and ten seconds.

It has been found preferable to start the cauterization procedure before the forceps 50 get too close to one another to prevent shorting out between them. In fact, it may be preferable to energize the electrodes while the balloon occluder assembly 15 is still between the forceps 50. The vascular tissue is instantaneously heated as the current passes from one electrode to the other. It is believed that the generated heat denatures or melts the collagen in the tissue, causing the tissue to fuse together and close the puncture. In addition, the heat generated may cause thrombosis or coagulation of blood which seals the puncture. After the vascular tissue has been thermally fused, the electrodes are deenergized.

FIG. 17A shows in detail how a puncture may be sealed if the forceps 50 are anchored as shown in FIG. 15A. The tissue from the femoral sheath 21 and adventitia 18 is drawn together and fused. The fused tissue forms a cap or plug over the puncture. The plug may include a weld 19 of the sheath 21 as well as a weld 29 of the adventitia layer 18, or the cap may be a homogenous mass of fused collagen. The gap between the media layers 17 is quickly closed with an arterial clot, and the intima layer 16 starts to grow closed a short time later.

If the forceps 50 only grasp the arterial sheath 21, it is possible that a cap or weld 19 of the sheath will only occur in the sheath, but that a plug will form below the sheath 21 and above the opening in the vessel wall to seal the puncture. Also, even though current may flow only between grasped portions of sheath 21, heat generated thereby may be conducted to the vessel wall 5 to also heat and fuse the adventitia layer 18.

After the seal has been formed, the thumb rest 32 is depressed once again, causing the forceps 50 to expand slightly, thus releasing the vascular tissue

(FIG. 17). The cautery device 7, followed by the cautery sheath 30, are removed from the body, leaving the vascular puncture hemostatically sealed (FIG. 18).

Additional preferred embodiments of the actuator element of the cautery device 7 are shown in FIGS. 6 - 8. FIG. 6 illustrates a cautery device 107 comprising a gripping handle 126, which pivots about a screw, causing a portion of the gripping handle to compress a spring and actuate the forceps 50. Similarly, FIG. 7 illustrates an additional preferred embodiment of the cautery device 207 comprising a rack and pinion mechanism 226 for actuating or moving the forceps 50 from a first position to a second position. FIG. 8 shows another preferred embodiment of the cautery device 307 wherein the gripping handle comprises a wedge which acts against an inclined plane 326 and compresses a spring when squeezed, actuating the forceps 50. Also contemplated by this invention are cautery devices comprising additional suitable mechanisms for actuating the forceps 50.

In addition to the balloon occluder assembly of the first preferred embodiment, the present invention contemplates the use of any other device, assembly or mechanism which will provide a backstop for the tissue surrounding the vascular puncture. The backstop element, the distal portion of which is located inside the puncture, essentially functions as an anchor or a positioning mechanism to provide positioning support and to help guide a hemostatic device to the puncture site.

In an additional preferred embodiment, the backstop element is a T-shaped occluder 114 adapted to be inserted into the vessel lumen 6 to provide positioning support for the tissue surrounding the vascular puncture and to temporarily occlude the puncture (FIGS. 19A & 19B). The purpose of providing positioning support to the tissue surrounding the

vascular puncture is to allow the forceps to more easily grasp the vascular tissue and to grasp only the proper tissue, i.e., to prevent the cautery forceps from grasping and sealing the entire vessel. The purpose of temporarily occluding the puncture is obviously to prevent blood or fluid loss.

The backstop element may be connected to a guiding shaft, such as the guiding shaft 108 as shown in FIGS. 19A & 19B. The guiding shaft 108, similar to the balloon shaft 8, allows the backstop element to be manipulated and controlled from outside the body and also provides a means for determining the depth of the puncture.

The T-shaped occluder 114 is made of a flexible, springy material. It may be either plastic pre-bent into a T shape or a coiled wire similar to that of conventional guide wires. The T-shaped occluder may have more horizontally extending legs than just the two shown. Prior to insertion (FIG. 19A), the T-shaped occluder is disposed in the guiding shaft 108 similar to the balloon shaft 8 of the first preferred embodiment. The radial compression of the guiding shaft 108 causes the horizontal portion of the T-shaped occluder to fold up. The folded-up horizontal portion forms the distal end of the T-shaped occluder. In use, the distal end of the occluder is pushed out of the guiding shaft 108, causing the folded-up portion to unfold and contact the interior surface of the vessel wall immediately proximate the puncture (FIG. 19B). The perpendicular vertical portion of the occluder extends out from the vessel lumen 6 through the puncture, into the guiding shaft 108 and to the skin surface. A spring 112 is used to move the T-shaped occluder from a first position to a second position. A locking mechanism 120 particularly a locking pin 122, is used to keep the T-shaped occluder in its first or second position.

Although it is preferable to use a backstop element which functions to provide positioning support and to temporarily occlude the puncture, it is not necessary. That is, another aspect of the present invention provides a method of sealing a vascular puncture wherein the introducer sheath is withdrawn from the vascular puncture, a cautery sheath is inserted and the distal end of the cautery device is then inserted into the cautery sheath and activated as previously described. If no backstop element is used, however, digital pressure may be required to temporarily stop the bleeding from the puncture.

In additional preferred embodiments, the means for forcing together biological tissue may include any conventional system or mechanism suitable for pulling, pushing or causing tissue to come together. In addition to forceps, one such means may be a vacuum system. In a vacuum system, the force of the suction causes the vascular tissue to be pulled into a contacting position. Other mechanical systems which push the tissue together may also be used.

In some methods of the invention, the tissue may not need to be grasped, or at least not pulled all the way together. It has been found that as heat is generated in, or thermally conducted to, the tissue surrounding the puncture, the tissue undergoes a sphinctering effect, closing upon itself to seal the artery. Depending on the size of the puncture, a radio frequency cautery device could be percutaneously inserted such that its electrode or electrodes were proximate the puncture site and then the radio frequency energy would cause this sphinctering effect and thrombosis of the blood to seal the opening. In this method, pressure would be applied to the vessel to restrict blood flow therethrough while the cauterization was performed.

Bipolar electrodes are preferred, although monopolar electrodes are also contemplated by the present invention. One of the prongs of the forceps 50 may thus comprise a monopolar electrode, or a separate monopolar electrode may be located proximate to the forceps, such that radio frequency energy can be applied to the biological tissue which is held in a contacting position by the forceps. When a monopolar electrode is used, the patient is grounded using a grounding pad. Alternately, a monopolar electrode may be placed in the center of the forceps 50, or used without the forceps 50 where the tissue can be treated without being grasped. When a monopolar electrode is used, most of the energy is concentrated, and most of the heat generation occurs, in the tissue contacting the electrode. However, energy is transmitted to deeper layers (such as through the arterial sheath 21 and into the vessel wall 5) as the current dissipates and moves toward the grounding pad, and this current then produces heating at the sites near the electrode where the current density is still sufficiently high.

Since the use of heat is the operative element in the process, the invention also contemplates delivering heat to the tissue by thermal conduction from a heated probe. Thus the energy that is directly conducted to the tissue may be electrical energy (either alternating current or direct current, including pulsed direct current) or thermal energy. Microwave energy may also be used to generate heat in the tissue, particularly if a probe is constructed with a microwave source or receptor at its operative tip.

Depending on how the heat is conducted to or generated in the tissue, and whether the tissue is grasped together, the heat will fuse the tissue in a variety of mechanisms, including fusing and cross-linking of collagen, coagulation of blood, and combinations thereof.

An additional preferred embodiment of the present invention contemplates the use of an internal plunger mechanism as a means for inflating the balloon 14. The internal plunger mechanism would fit within the shaft 8 and would use the air already present in the shaft to inflate the balloon. The mechanism would incorporate a check valve to keep the balloon inflated and would thus alleviate the need for the removable hub 10, syringe 12 and check valve assembly 20 which comprise the inflation means of the first preferred embodiment.

The present invention incorporates an assembly for temporarily occluding a vascular puncture, as discussed above, which, when used with a hemostatic device or composition, effectively and efficiently seals a vascular or other percutaneous puncture. Additional aspects of the present invention include the use of any suitable hemostatic device or composition known in the art in conjunction with the occluding assembly mentioned above. Although the preferred hemostatic means of the present invention is the cautery device 7, additional devices or compositions which are capable of hemostatically sealing a vascular puncture, such as a tissue adhesive, a thrombolic agent, a vascular clip, sutures or a suturing device, are contemplated for use with the occluder assembly.

Another aspect of the present invention is to provide an assembly adapted to guide a hemostatic means to a puncture site. The first preferred embodiment disclosed the use of a balloon occluder assembly. Any assembly, however, comprising an elongated shaft having a positioning mechanism at the distal end thereof and a means for controlling or manipulating the positioning mechanism at the proximal end thereof, wherein the distal end of the elongated shaft is insertable into the lumen of a vessel and the positioning mechanism is configured to anchor the distal end of the assembly inside the vessel is contemplated. Any such assembly

should further prevent entry of the hemostatic means into the vessel through the puncture site. Preferred embodiments of such an assembly include the balloon occluder assembly and the T-shaped occluder device.

Another aspect of the present invention is to provide an assembly adapted to determine the depth of a percutaneous vascular puncture comprising an elongated shaft having markings thereon and a positioning mechanism at the distal end thereof. Any such assembly adapted to measure the depth of a percutaneous vascular puncture from the level of the skin when the distal end of the elongated shaft is inserted into the lumen of the vessel and the positioning mechanism is anchored in the vessel is acceptable.

An additional aspect of the present invention is to provide a method of sealing a vascular puncture which does not require the use of a cautery sheath or dilator. Instead, the original introducer sheath may be used in place of the cautery sheath if it is withdrawn slightly from the puncture site so that it is not in the vessel lumen 6.

It should be appreciated that the apparatus and methods of the present invention are capable of being incorporated in the form of a variety of embodiments, only a few of which have been illustrated and described above. The invention may be embodied in other forms without departing from its spirit or essential characteristics. In some aspects of the invention, other energy sources could be used to generate heat in the tissue or cause thrombosis of the blood to seal the puncture. The described embodiments are to be considered in all respects only as illustrative and not restrictive and the scope of the invention is, therefore, indicated by all the appended claims rather than by the foregoing description. All changes which come within the meaning and range of equivalency of the claims are to be embraced within their scope.

WE CLAIM:

1. A method of sealing a vascular opening comprising the steps of:

a) percutaneously inserting a probe adjacent to the vascular opening;
b) conducting energy from said probe directly to tissue adjacent the probe in an amount sufficient to cauterize said tissue to thereby close said vascular opening; and
c) removing said probe.

2. The method of Claim 1 wherein the probe transfers energy to the tissue by thermal conduction.

3. The method of Claim 1 wherein the probe conducts electrical energy to the tissue, and the tissue is heated due to its electrical resistance.

4. The method of Claim 1 wherein the probe conducts alternating current electrical energy to the tissue.

5. The method of Claim 4 wherein the alternating current conducted to the tissue is radio frequency energy.

6. The method of Claim 4 wherein the alternating current conducted to the tissue has a frequency between 25 kHz and 1,000 kHz.

7. The method of Claim 4 wherein the probe transfers microwave energy to cauterize the tissue.

8. The method of Claim 3 wherein the probe conducts direct current electrical energy to the tissue.

9. The method of Claim 8 wherein the direct current energy is provided in pulsed form.

10. The method of Claim 1 further comprising the step of spreading subcutaneous tissue above the vascular opening.

11. An apparatus for sealing a vascular opening comprising:

a) a probe sized to be percutaneously inserted adjacent the vascular opening; and
b) a connector for connecting the probe to an energy supply source;
c) the probe being configured to conduct energy directly to tissue adjacent the probe to cause heating of tissue surrounding the vascular opening to close said opening.

12. The apparatus of Claim 11 further comprising a guide to direct the probe to the vascular opening.

13. A method of sealing a vascular opening comprising the step of:

a) delivering energy to the vascular wall, resulting in local heating of bodily material external to the intima layer of the vessel to achieve hemostasis without substantially heating the intima layer of the vessel.

14. The method of Claim 13 wherein collagen present in the heated material fuses to seal the vascular opening.

15. The method of Claim 13 wherein the bodily material comprises tissue.

16. The method of Claim 13 wherein collagen and blood in the heated material is heated resulting in fusion of the collagen and coagulation of the blood to seal the vascular opening.

17. The method of Claim 13 wherein blood present in the heated material coagulates to seal the vascular opening.

18. An apparatus for sealing a vascular opening comprising an electrical conductor connectable to an electrical current and configured to deliver said electrical current through subcutaneous tissue to effect closing of the opening in the vessel wall.

19. A method of sealing an opening in a vessel wall comprising the step of delivering electrical current to the vascular tissue around the opening, said current effecting closure of the vessel wall to seal said opening.

20. The method of Claim 19 wherein the current is delivered by at least one electrode which is in direct contact with the vascular tissue that closes to seal said opening.

21. The method of Claim 19 wherein the vessel wall is surrounded by a vascular sheath and the current is delivered by at least one electrode that penetrates the vascular sheath to contact the vascular wall.

22. The method of Claim 19 wherein the vessel wall is surrounded by a vascular sheath and the

current is delivered by an electrode that contacts and delivers energy to the vascular sheath.

23. The method of Claim 19 wherein heat is generated from delivery of the current and closure is effected by thermal conduction of said heat to the vessel wall.

24. A method of sealing an opening in a vessel wall surrounded by an arterial sheath having an opening therethrough above the opening in the vessel wall comprising the steps of:

a) effecting a seal of the opening of the arterial sheath and

b) creating an adhering plug to seal the opening in the vessel wall.

25. The method of Claim 24 wherein the plug is created below the arterial sheath and above the opening.

26. The method of Claim 24 wherein the plug is created on the arterial sheath.

27. A method of sealing an opening in a vessel wall surrounded by an arterial sheath comprising the step of delivering energy through the arterial sheath to the vessel wall sufficient to cauterize the vessel wall to seal the opening.

28. The method of Claim 27 wherein the energy comprises electrical current.

29. The method of Claim 28 wherein the electrical current is delivered by an electrode which is in contact with the arterial sheath.

30. The method of Claim 27 wherein the electrical current is delivered by an electrode which is in contact with the vessel wall.

31. An apparatus for sealing an opening in a vessel wall comprising:

a) an energy delivery probe for conducting energy directly to tissue surrounding said opening, and

b) means for spreading the subcutaneous tissue superficial to the surface of the vessel wall, said spreading means being capable of spreading the tissue to an opening dimension that is both larger than the opening in the vessel wall and larger than the dimension of the portion of the energy delivery probe used to contact the tissue surrounding the opening.

32. A method of sealing an opening in a vessel wall comprising the step of delivering energy to the vascular tissue, causing the vascular tissue to contract upon itself resulting in a sphinctering effect causing closure of said opening.

33. An apparatus for the percutaneous medical treatment of biological tissue, said apparatus comprising:

a) a plurality of electrodes connectable to a radio frequency power source, said electrodes adapted to engage biological tissue at spaced points; and

b) a lumen connected to the electrodes for guiding the electrodes to the biological tissue at said

spaced points, said apparatus adapted to thermally fuse together said biological tissue.

34. An apparatus for the medical treatment of a percutaneous vascular puncture with an electrical current comprising:

a) a cautery device comprising:

i) a means for forcing together biological tissue surrounding a percutaneous vascular puncture; and

ii) at least one electrode connectable to a radio frequency power source such that an electrical current may flow through the tissue, thermally fusing the tissue together.

35. The apparatus of Claim 34 wherein the means for forcing together the tissue comprises at least two forceps adapted to grasp and pull the tissue together.

36. The apparatus of Claim 35 wherein one of the forceps comprises the at least one electrode.

37. The apparatus of Claim 34 wherein the at least one electrode comprises a monopolar electrode.

38. The apparatus of Claim 34 wherein the at least one electrode comprises two bipolar electrodes.

39. The apparatus of Claim 34 further comprising an activating switch element wherein said switch element activates the electrical current flow to the at least one electrode.

40. The apparatus of Claim 34 wherein the radio frequency power source provides energy in the range of 300 kHz to 1,000 kHz.

41. The apparatus of Claim 34 wherein the cautery device is disposable.

42. The apparatus of Claim 34 further comprising a backstop element which provides positioning support to the vascular tissue surrounding a vascular puncture.

43. The apparatus of Claim 42 wherein the backstop element comprises a balloon occluder assembly comprising a balloon shaft having a balloon at the distal end thereof.

44. The apparatus of Claim 35 wherein the backstop element comprises an inverted T-shaped element adapted to be inserted into the lumen of the vessel, the horizontal portion of the T-shaped element being adapted for contacting with the interior surface of the lumen immediately proximate the puncture and the perpendicular vertical portion of the T-shaped element being adapted to extend from the lumen of the vessel out through the skin.

45. The apparatus of Claim 35 wherein the forceps have gripping portions at the distal end thereof, said forceps comprising electrodes, and the device further comprises:

a) a retaining tubular housing;

b) a gripping handle; and

c) an actuator element to move said metal forceps from a first position to a second position.

46. The apparatus of Claim 45 wherein the actuating element comprises a spring on the proximal end of the gripping handle and a thumb rest disposed at the proximal end of the spring.

47. The apparatus of Claim 45 wherein the gripping handle and actuating element comprise a pivoting element whereby a portion of the gripping handle actuates the forceps.

48. The apparatus of Claim 45 wherein the gripping handle and actuating element comprise a rack and pinion mechanism for actuating the metal forceps.

49. The apparatus of Claim 45 wherein the gripping handle and actuating element comprise a wedge which acts against an inclined plane to actuate the metal forceps.

50. The apparatus of Claim 42 further comprising a guiding shaft connected to the back stop element and a dilator and a cautery sheath, said dilator and cautery sheath adapted to be inserted over the guiding shaft.

51. The apparatus of Claim 43 wherein the balloon occluder assembly further comprises a balloon protector around the balloon.

52. The apparatus of Claim 43 wherein the balloon occluder assembly further comprises a check valve assembly at the proximal end of the balloon shaft.

53. The apparatus of Claim 43 wherein the balloon occluder assembly further comprises a removable hub.

54. The apparatus of Claim 43 further comprising a means for inflating said balloon.

55. A cautery device for cauterizing a puncture in a vessel within the body of a patient comprising:

a) a gripping handle;

b) a tubular retaining housing;

c) metal forceps comprising electrodes disposed within said tubular retaining housing at a first position and extending beyond the distal end of said tubular retaining housing at a second position;

d) an actuator element to move said metal forceps from said first to said second position;

e) a connector element adapted to connect the forceps to a radio frequency power source; and

f) a lumen associated with said tubular retaining housing for guiding said forceps to said puncture.

56. The device of Claim 55 wherein the connector element comprises detachable electrical leads.

57. The device of Claim 55 wherein the metal forceps are insulated except at the distal tip, said distal tip further comprising a gripping portion of a shape that is advantageous for gripping biological tissue.

58. The device of Claim 55 wherein the lumen extends through the gripping handle and the tubular retaining housing.

59. The device of Claim 55 wherein the lumen and the tubular retaining housing are formed together as a triple lumen tube.

60. The device of Claim 55 wherein the metal forceps comprise bipolar electrode elements.

61. An assembly for temporarily occluding a vascular puncture comprising an elongated shaft having markings thereon to determine the depth of the puncture from the surface of the skin and a balloon at the distal end thereof and a means at the proximal end of the shaft for inflating said balloon, said inflated balloon being sized and shaped to occluder the vascular puncture from within the vessel.

62. The assembly of Claim 61 further comprising a check valve assembly to prevent deflation of the balloon.

63. The assembly of Claim 62 wherein the diameter of the check valve assembly is less than 3 mm.

64. An assembly adapted to guide a hemostatic means to a puncture site, said assembly comprising an elongated shaft having markings thereon to determine the depth of the puncture from the surface of the skin and having a positioning mechanism at the distal end thereof, the distal end of said elongated shaft being insertable into the lumen of a vessel, the positioning mechanism being configured to anchor the distal end of the assembly inside the vessel and to prevent entry of the hemostatic means into the vessel through the puncture site.

65. The assembly of Claim 64 wherein the positioning mechanism comprises a balloon.

66. The assembly of Claim 64 wherein the positioning mechanism comprises a T-shaped occluder.

67. An assembly adapted to determine the depth of a percutaneous vascular puncture comprising an elongated shaft having markings thereon, a positioning

mechanism at the distal end thereof, the assembly adapted to measure the depth of a percutaneous vascular puncture from the level of the skin when said distal end of said elongated shaft is inserted into the lumen of a vessel and said positioning mechanism is anchored in the vessel.

68. A method for closing and sealing a vascular opening comprising:

a) holding the vascular tissue surrounding a vascular opening in a contacting position; and

b) applying energy to the vascular tissue immediately proximate the opening, said energy being sufficient to thermally fuse the tissue and seal the vascular opening.

69. The method of Claim 68 wherein the steps are performed after a medical device has been removed from a vascular puncture.

70. The method of Claim 68 wherein the method is performed percutaneously.

71. The method of Claim 68 wherein the energy is radio frequency energy.

72. The method of Claim 71 wherein said radio frequency energy is sufficient to thermally fuse the tissue and seal the opening while avoiding coagulating the fluid in the vessel.

73. The method of Claim 68 wherein the method comprises grasping and bringing into a contacting position the vascular tissue surrounding the vascular opening.

74. The method of Claim 73 wherein two or more forceps are used to grasp the tissues surrounding the vascular opening.

75. The method of Claim 68 wherein the method comprises keeping the interior surfaces of the vascular tissue separated.

76. A method of closing and sealing a vascular puncture comprising:

a) guiding a device comprising a cautery probe tip to the site of a puncture;

b) grasping together the tissues immediately proximate the puncture site into a contacting position; and

c) generating a cauterizing discharge from said probe tip to the tissues immediately proximate the puncture site, said cauterizing discharge being sufficient to thermally fuse the puncture.

77. The method of Claim 76 wherein the step of guiding a device to the site of a puncture includes the step of advancing the device through a cautery sheath.

78. The method of Claim 76 wherein positioning support is provided to the tissue immediately proximate the puncture.

79. The method of Claim 78 wherein a balloon occluder assembly is used to provide positioning support to the tissue.

80. The method of Claim 78 wherein a T-shaped occluder is used to provide positioning support to the tissue.

81. A method for medical treatment of a vascular puncture comprising the steps of:

a) advancing an elongated cautery probe having two or more forceps at its distal end to a vascular puncture site, said forceps comprising electrodes;

b) causing the forceps to grip and pull together the tissue surrounding the puncture; and

c) establishing a current flow between said electrodes, whereby said tissue surrounding the vascular puncture is electrically heated by said current flow thereby thermally fusing the tissue together.

82. A method of treating a percutaneous opening in a vessel wall comprising the steps of:

a) advancing a shaft having an inflatable balloon at the distal end thereof through a catheter introducer sheath wherein the distal end of the shaft extends through the opening into the lumen of the vessel;

b) inflating said balloon to a size sufficiently large to occlude the opening;

c) retracting said balloon and introducer sheath until the balloon abuts the tissue surrounding the opening in the vessel, thereby occluding the opening;

d) removing the introducer sheath from the vessel;

e) inserting the distal end of a cautery device into the body;

f) grasping and pulling together the tissue surrounding the opening with the metal forceps, the inflated balloon providing a back stop for the forceps;

g) deflating the balloon and withdrawing the shaft from the vessel after the tissue has been grasped and pulled together by the forceps; and

h) applying radio frequency energy to the tissue surrounding the opening, said energy being sufficient to thermally fuse and seal the tissue together.

83. The method of Claim 82 wherein the balloon shaft is used to guide the cautery device to the opening.

84. The method of Claim 82 wherein a dilator and a cautery sheath are introduced into the skin after the introducer sheath has been removed, the dilator being removed prior to the insertion of the cautery device.

85. The method of Claim 82 wherein the balloon shaft and the cautery sheath both contain a series of markings for determining the distance from the surface of the skin to the site of the vascular opening.

86. A method of using radio frequency energy to close a vascular puncture comprising the steps of:

a) guiding a cautery device to the site of the vascular puncture, said cautery device having forceps at the distal end thereof and an actuating mechanism for causing the forceps to grasp the tissue surrounding the puncture;

b) causing the forceps to grasp and pull together the tissues surrounding the puncture, said forceps comprising electrodes connected to a radio frequency energy source;

c) activating the radio frequency energy source, thereby causing the tissue surrounding the puncture to fuse together; and

d) removing the cautery device from the body.

87. The method of Claim 86 wherein the cautery device is guided to the site of the vascular puncture through a cautery sheath.

88. A method of using radio frequency energy to percutaneously close a vascular puncture comprising the steps of:

a) applying pressure to the vessel to restrict blood flow therethrough;

b) percutaneously inserting an electrode to a position proximate the puncture site; and

c) using radio frequency energy to cause thrombosis of the blood to seal the opening.

89. The method of Claim 88 further comprising the step of forcing the vascular tissue surrounding the puncture site towards a closed position prior to using the radio frequency energy.

90. A method of temporarily occluding a vascular puncture comprising advancing a shaft having markings thereon to determine the depth of the puncture from the surface of the skin and an inflatable balloon at its distal end into the lumen of a vessel, inflating the balloon and retracting the inflated balloon until it abuts the puncture, thereby preventing fluid loss from the puncture.

91. A method of guiding a device for sealing vascular punctures to the site of a vascular puncture comprising advancing a shaft having a positioning mechanism at its distal end into the lumen of a vessel, anchoring the positioning mechanism so that it abuts the puncture, thereby locating and identifying the puncture site, and using the shaft to guide the sealing device to the puncture site.

92. A method for determining the depth of a percutaneous vascular puncture comprising the steps of advancing a shaft having markings thereon to determine the depth of the puncture from the surface of the skin and a positioning mechanism at its distal end into the lumen of a vessel, said shaft having on it a system for measuring length, anchoring the positioning mechanism so that it abuts the puncture, said system providing an indication of the depth of the vascular puncture from the surface of the skin.

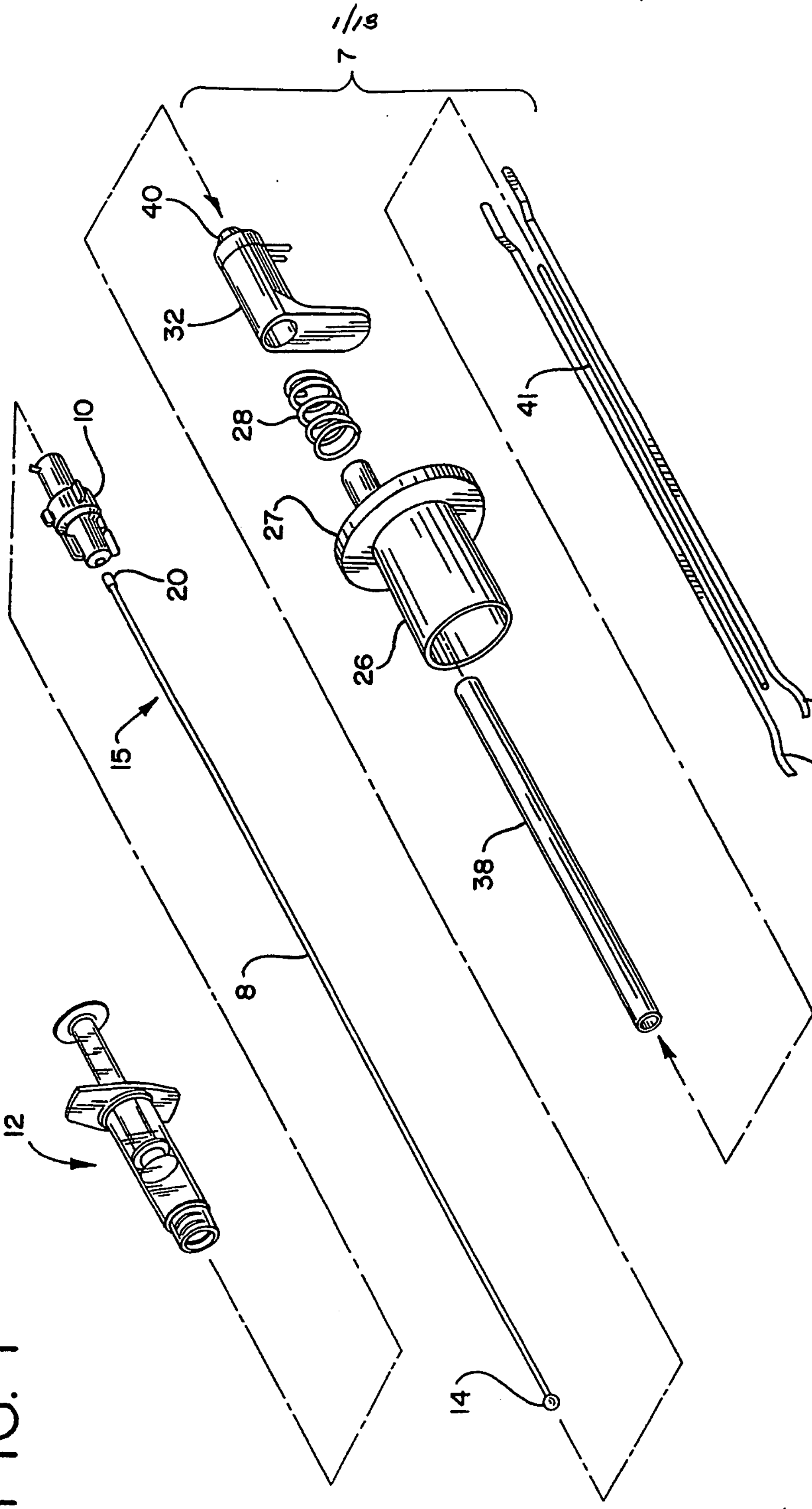


FIG. 1

SUBSTITUTE SHEET

FIG. 5

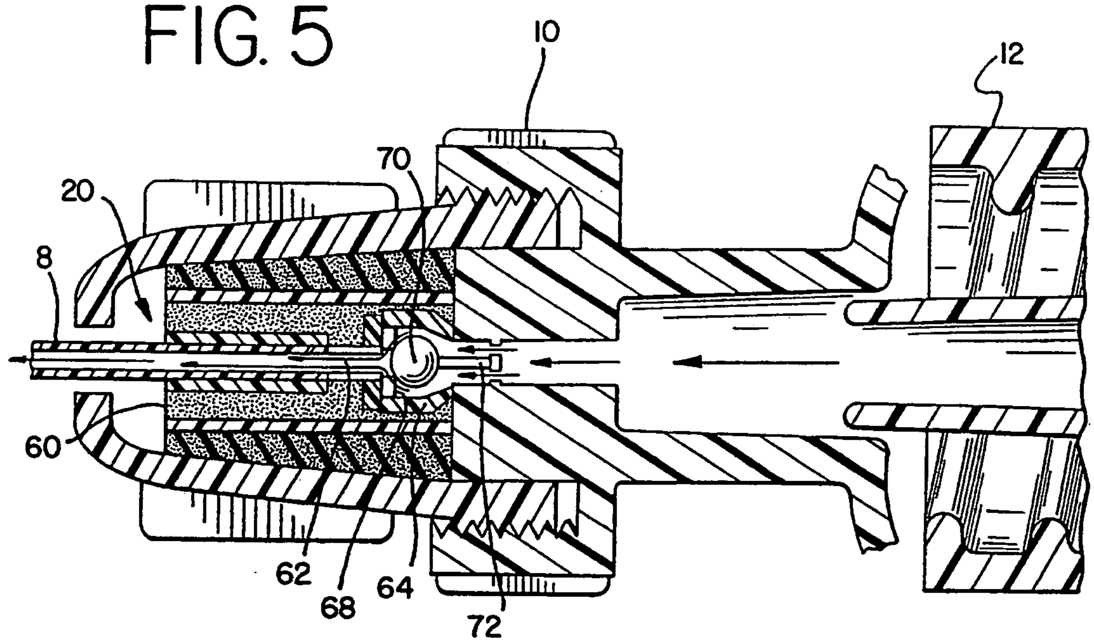


FIG. 2

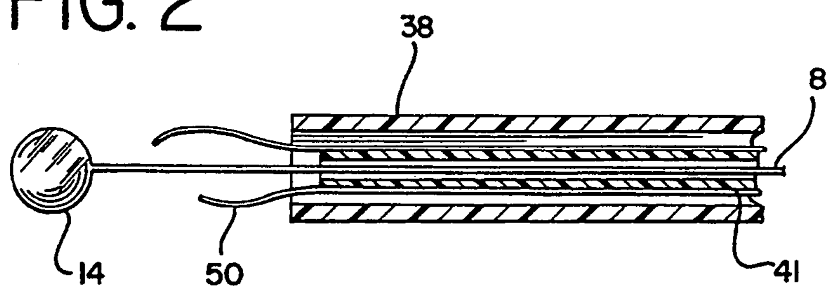


FIG. 3

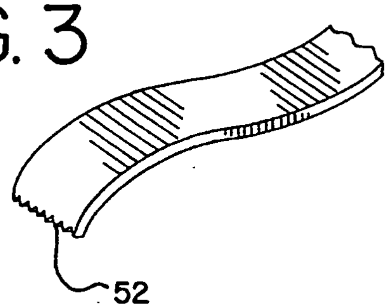


FIG. 4

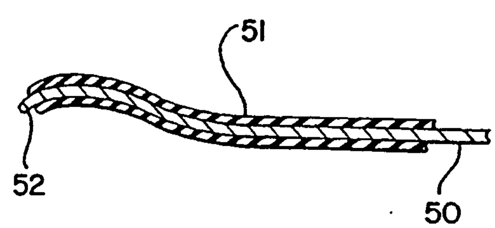


FIG. 8

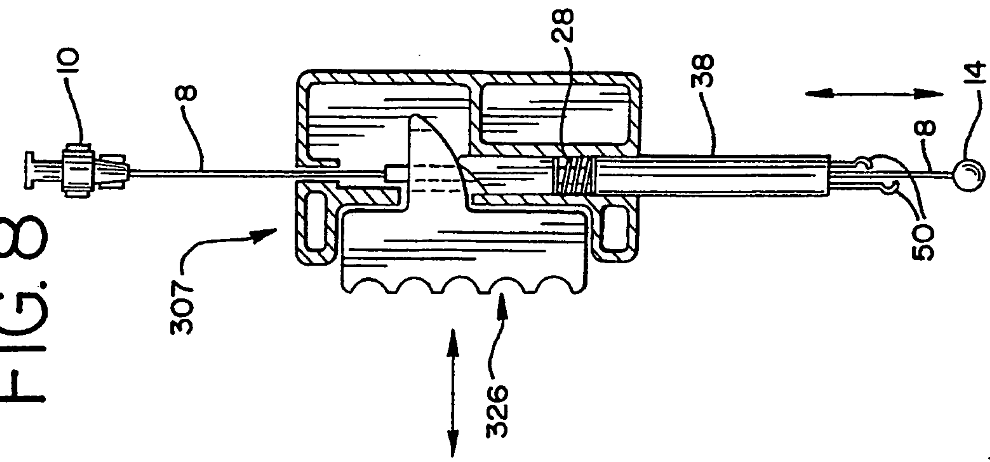


FIG. 7

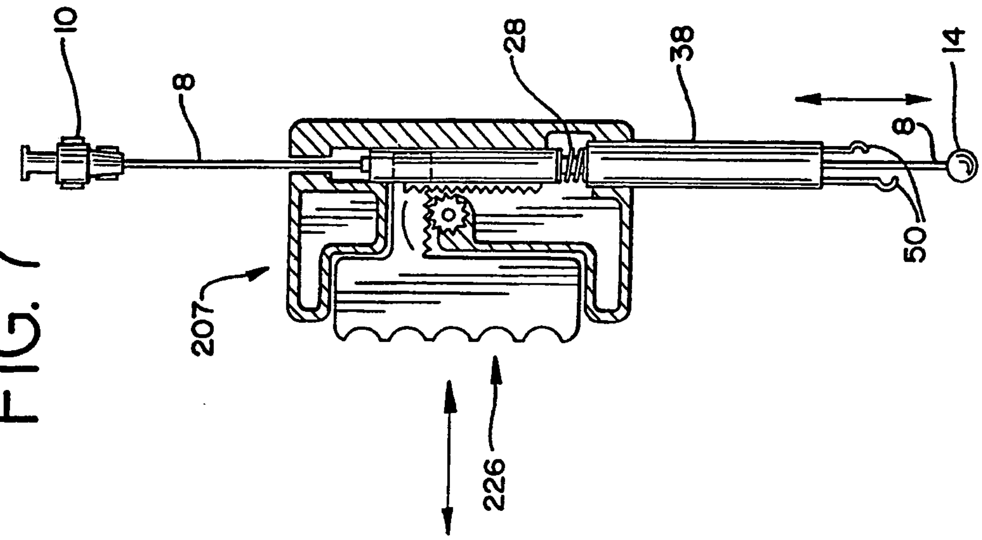
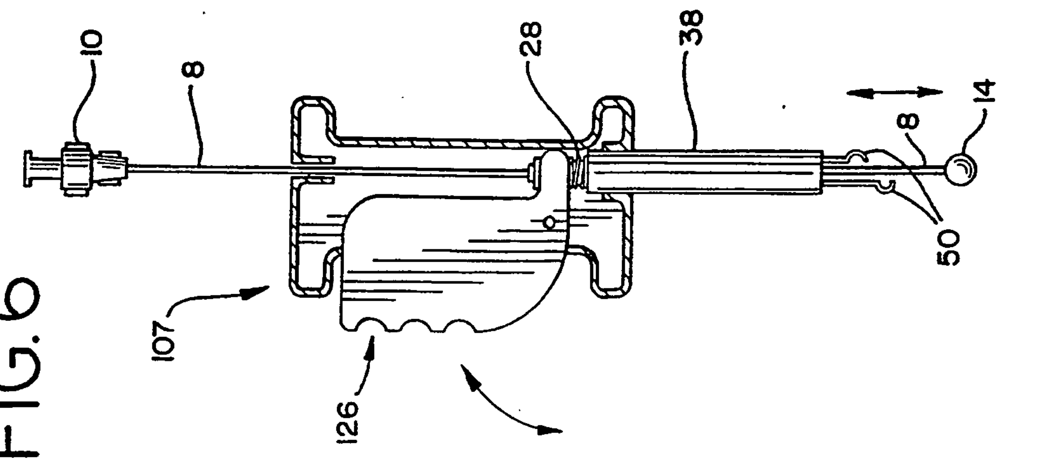


FIG. 6



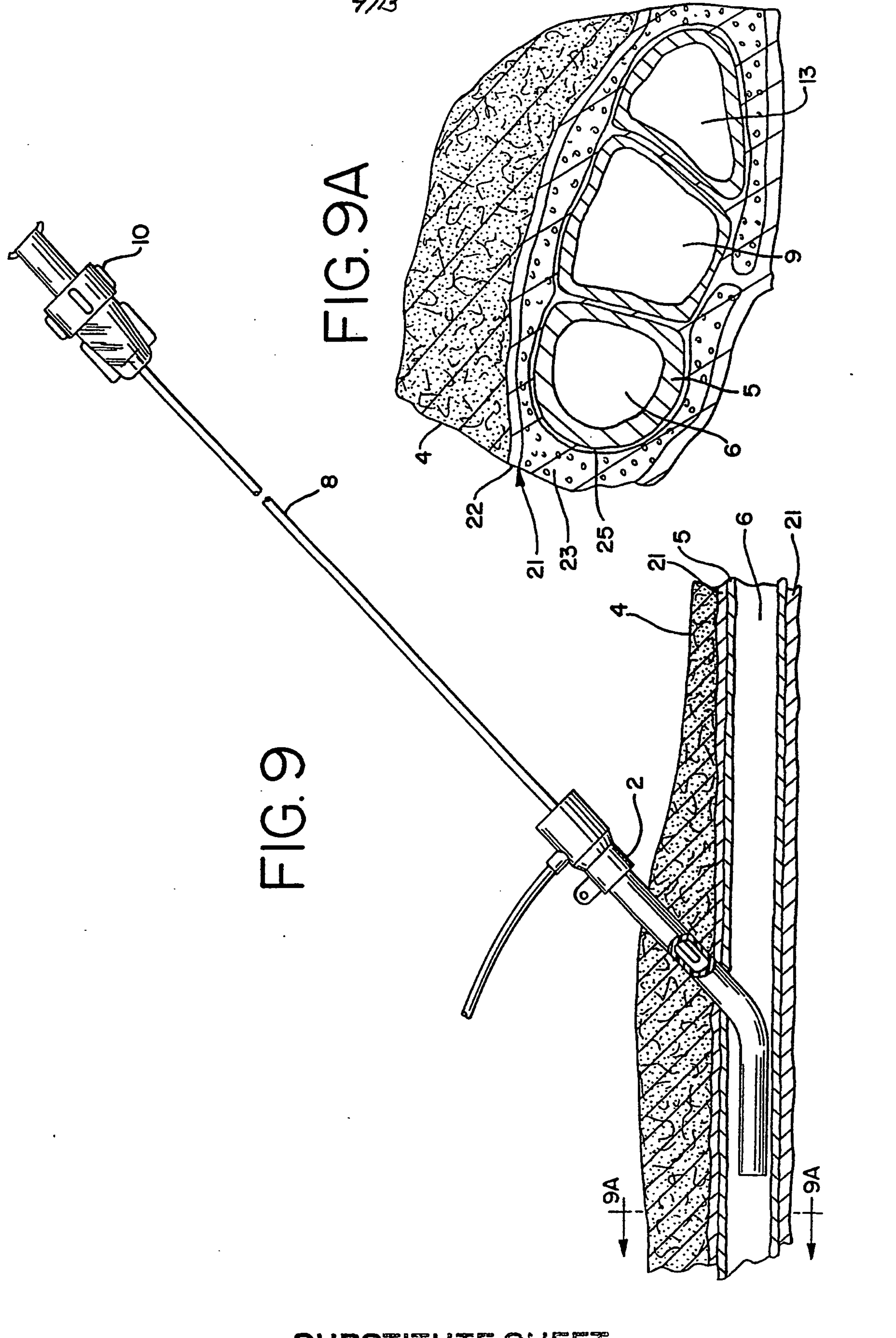


FIG. 9

FIG. 9A

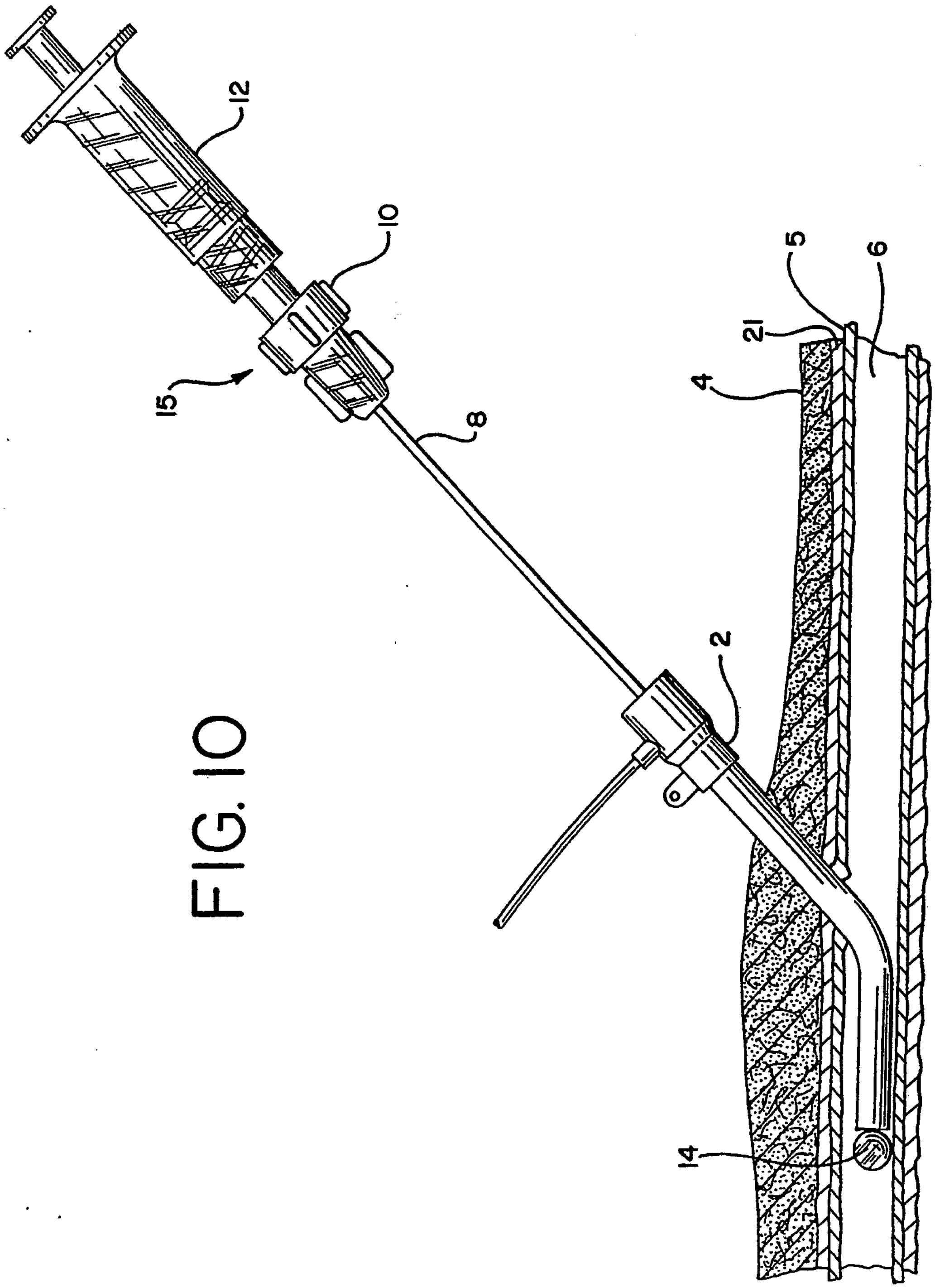


FIG. 10

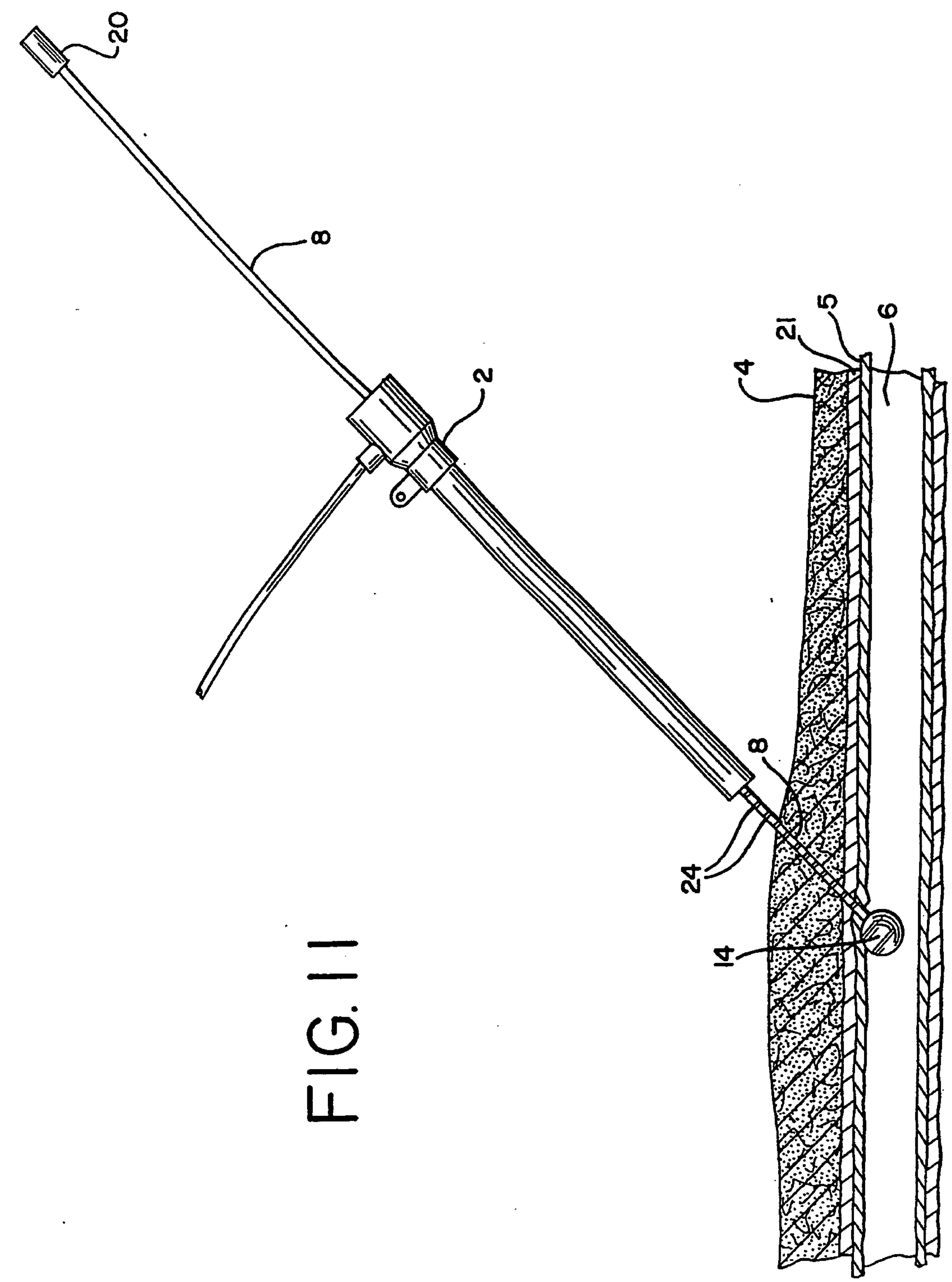


FIG. 11

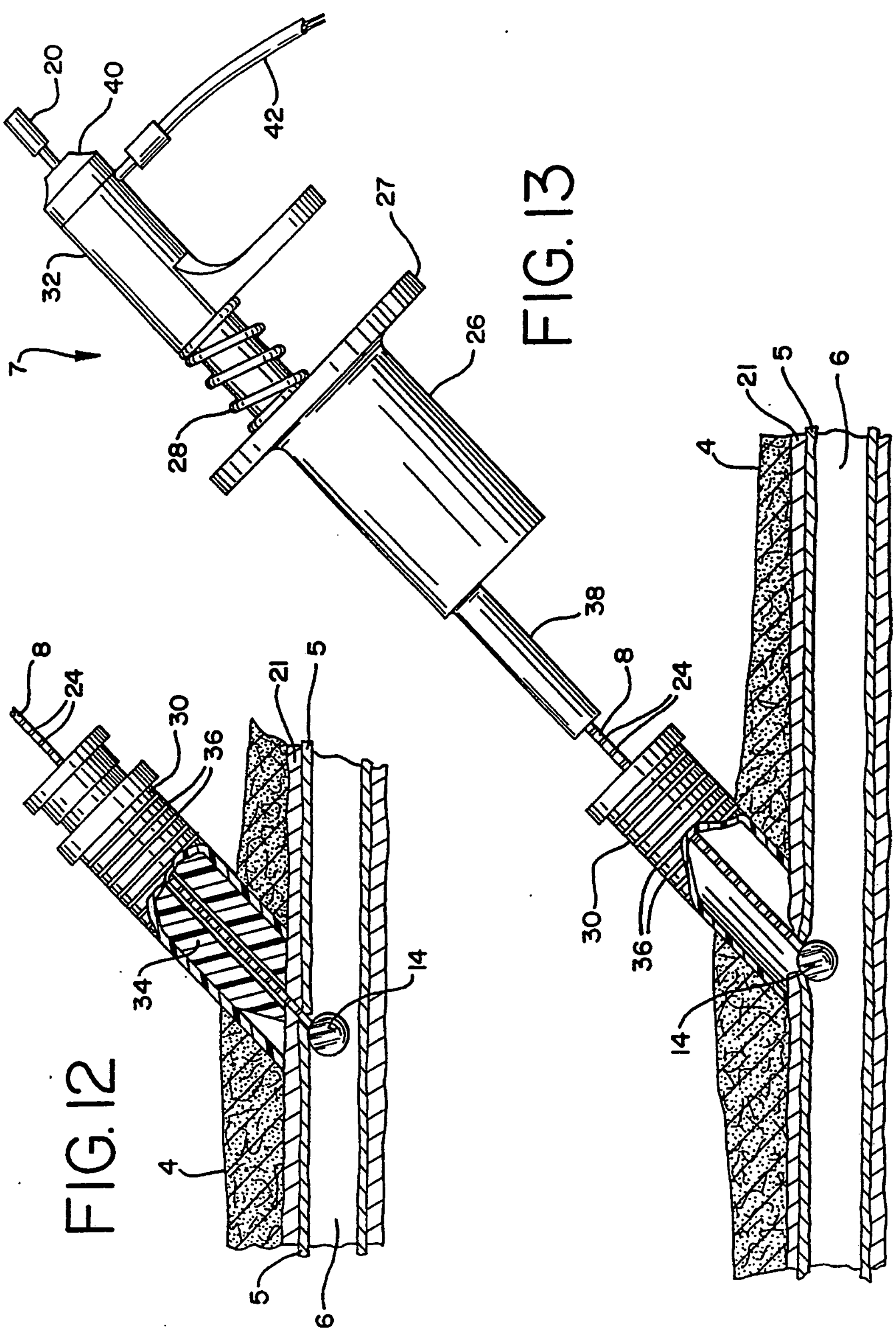


FIG. 13

FIG. 12

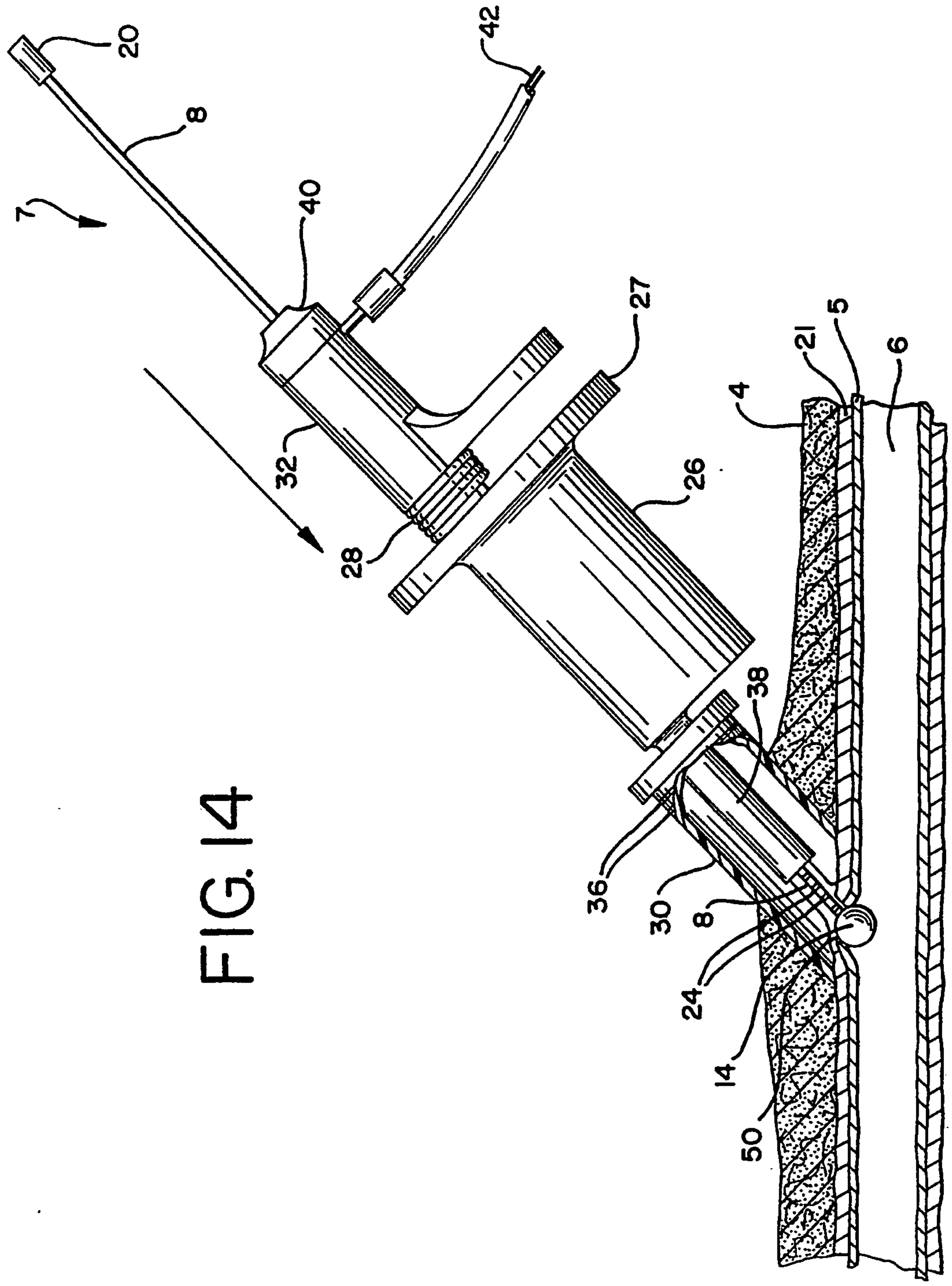


FIG. 14

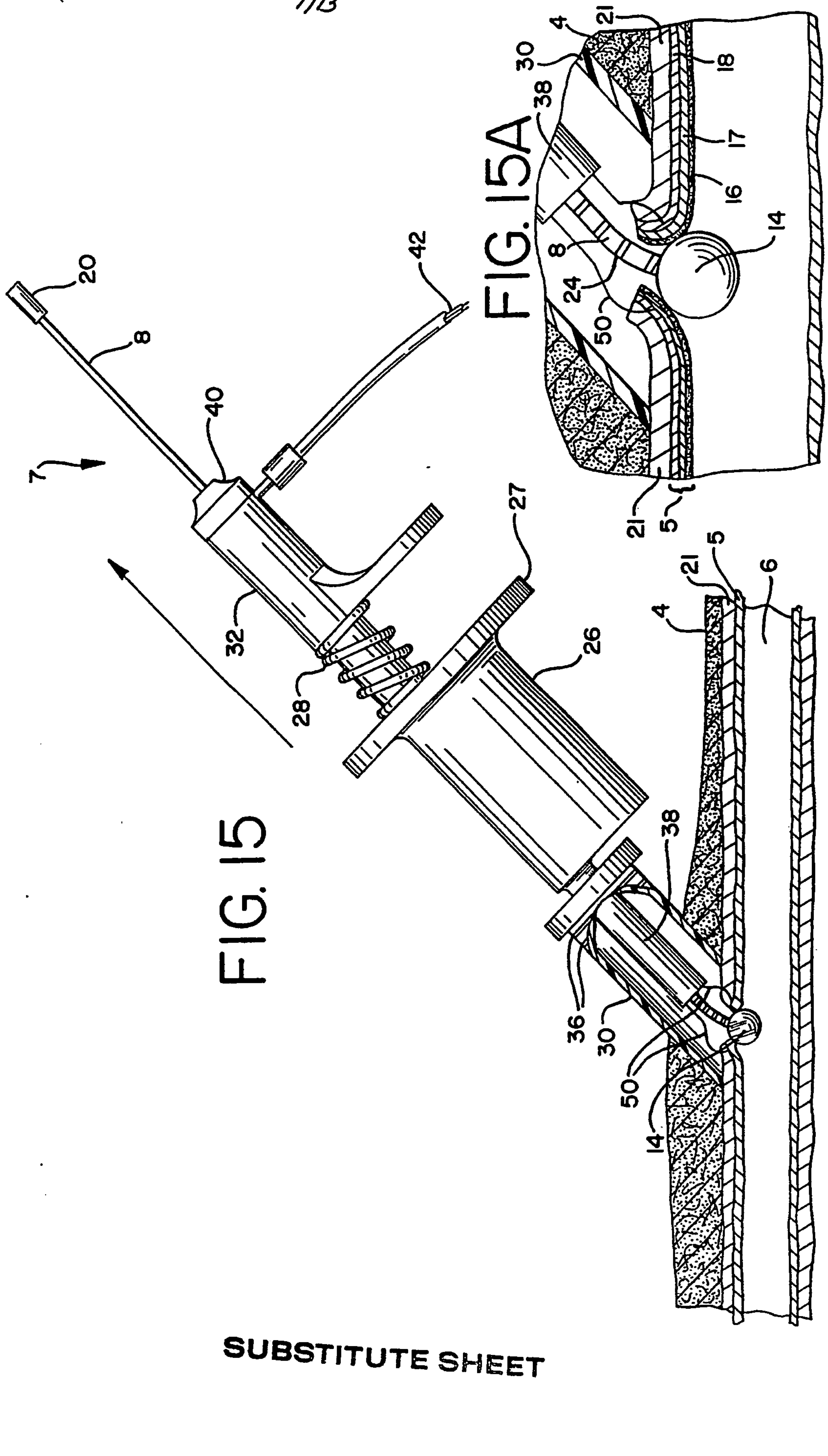


FIG. 15

FIG. 15A

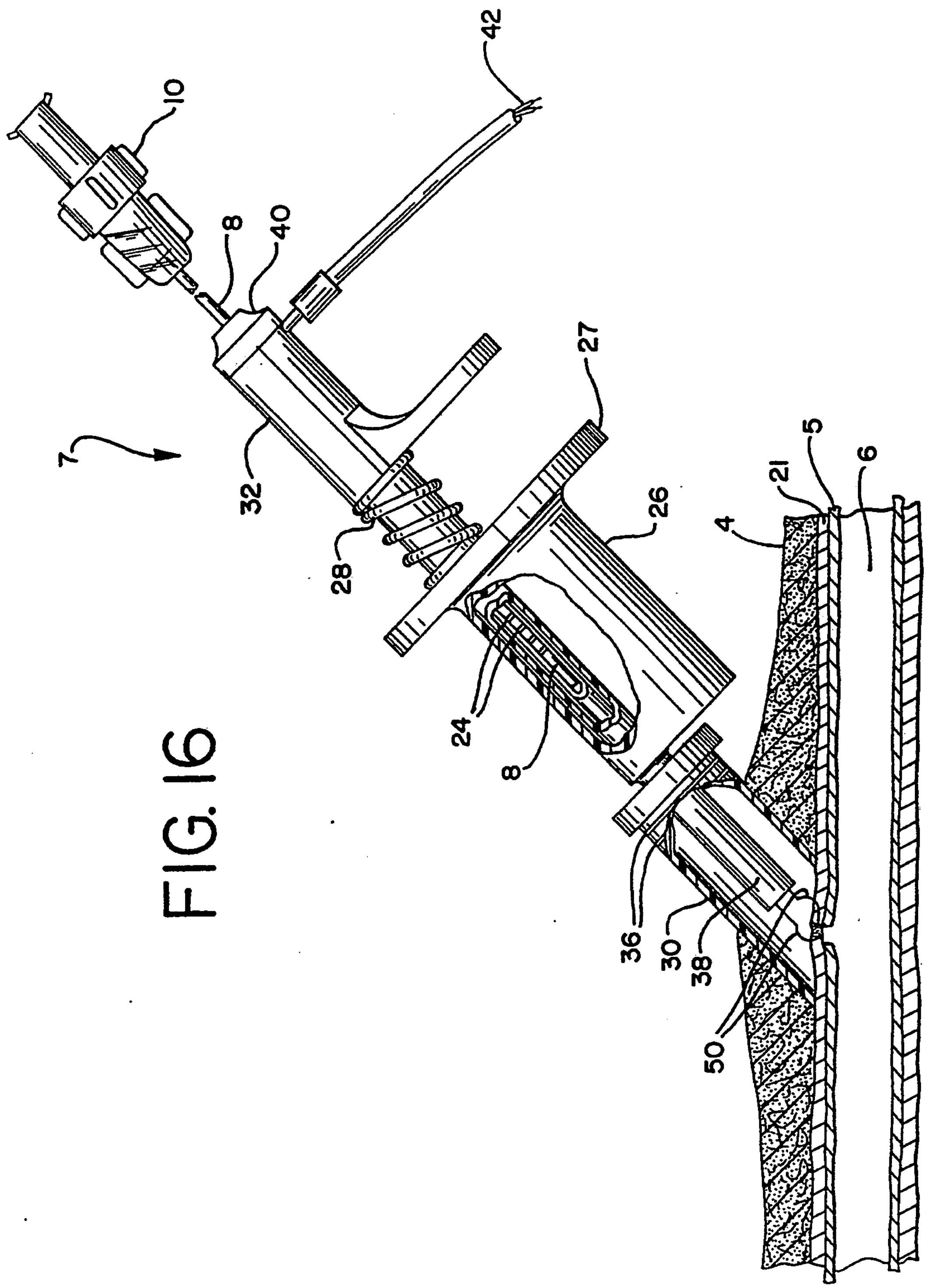


FIG. 16

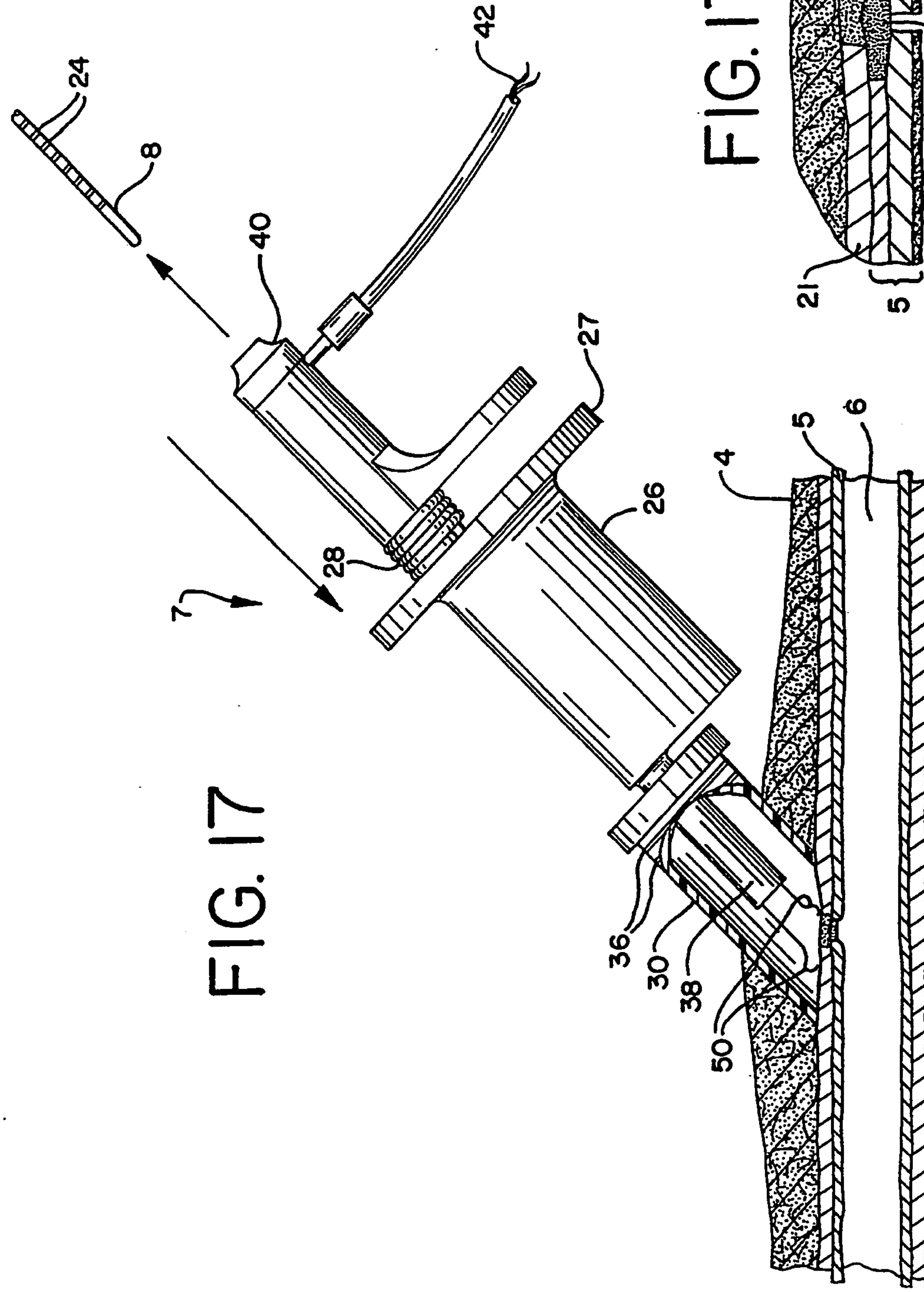


FIG. 17

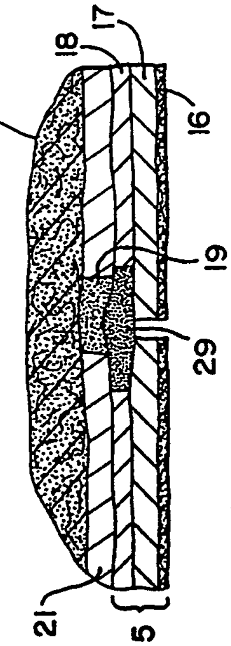


FIG. 17A

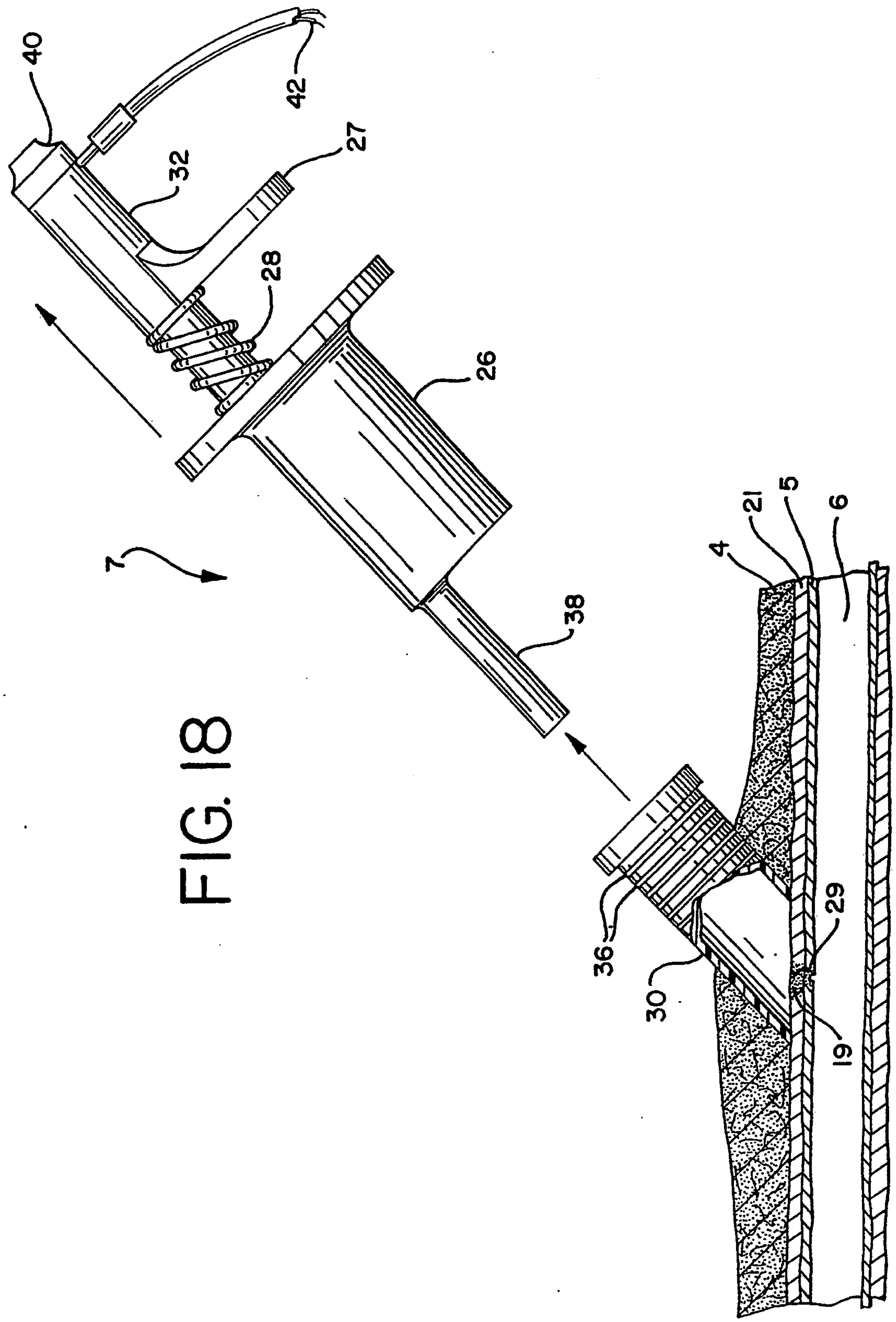


FIG. 18

FIG. 19A

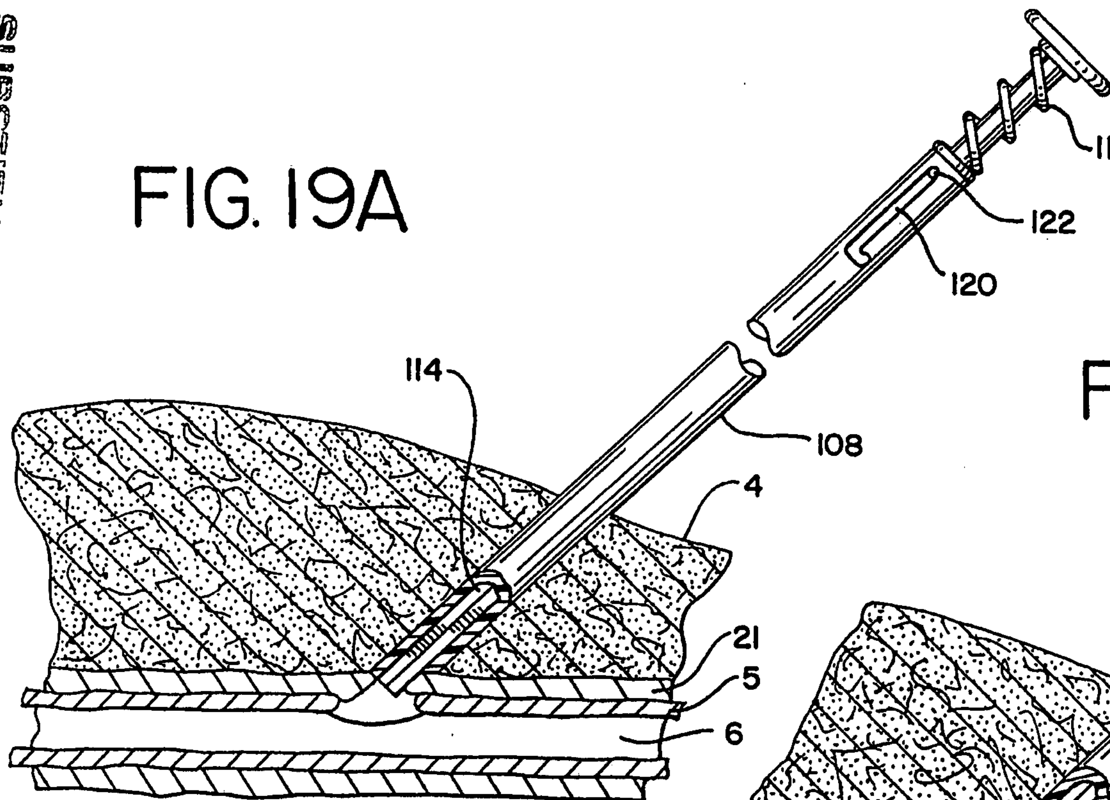
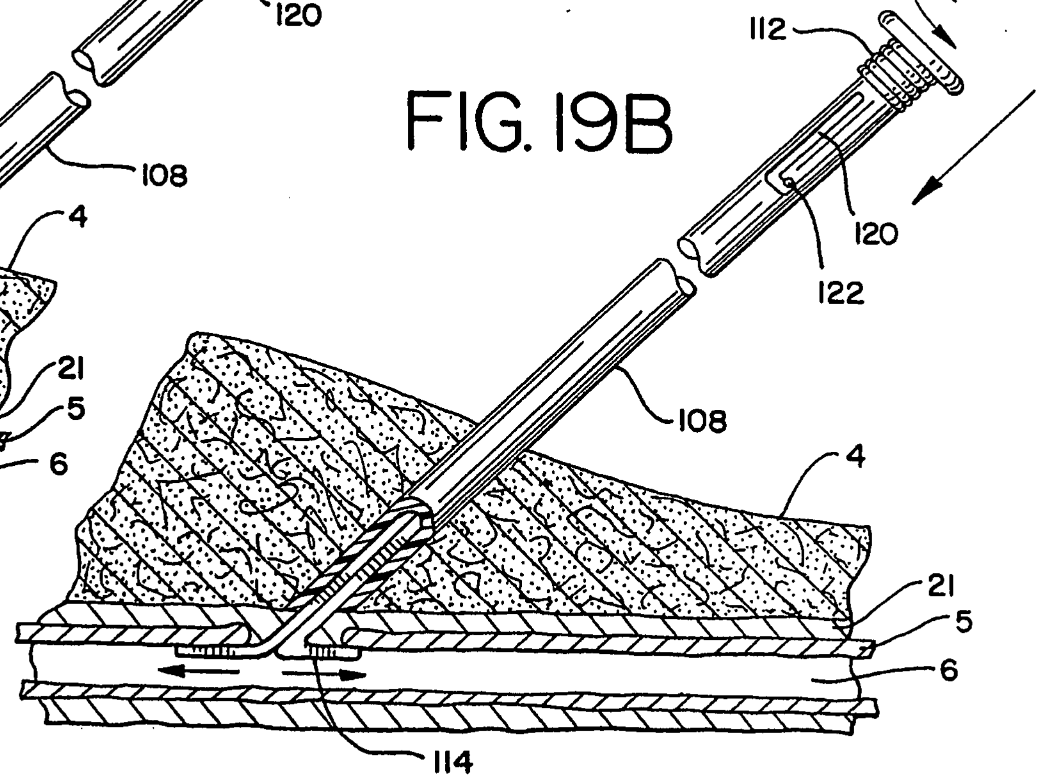


FIG. 19B



INTERNATIONAL SEARCH REPORT

International application No.
PCT/US93/03849

A. CLASSIFICATION OF SUBJECT MATTER

IPC(5) : A61B 17/36
US CL : 606/50, 194

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. CL: 606/32,37,40,41,49,164,51,52,191,192,211
128/784,785,786

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X Y	US, A, 4,716,897 (Noguchi et al.) 05 January 1988. see entire document.	1,5,11,13-21,23,27-31 2-4,6-10,12,24-26,32-34,55,56,22
X Y	US, A, 4,938,761 (Ensslin) 03 June 1990 see entire document.	34-37,41,68,73,76 38-40,42-45,49,55-57,69-72,74,75

[X] Further documents are listed in the continuation of Box C. [ ] See patent family annex.

* Special categories of cited documents:

"A" document defining the general state of the art which is not considered to be part of particular relevance

"E" earlier document published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&" document member of the same patent family

Date of the actual completion of the international search
25 JUNE 1993

Date of mailing of the international search report
03 AUG 1993

Name and mailing address of the ISA/US
Commissioner of Patents and Trademarks
Box PCT
Washington, D.C. 20231

Facsimile No. NOT APPLICABLE

Authorized officer
SAMUEL GILBERT

Telephone No. (703) 308-3553

C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X Y	US, A, 4,016,881 (Rioux eet al.) 12 April 1977. see entire document.	34,35,39,40,41,45-47,68,73,76-78,81,86-89 42-44,48-59,69-72,74,75,79,80
Y	US, A, 5,013,312 (Parins et al.) 07 May 1991 see abstract.	1-10
Y	US, A, 4,198,957 (Cage et al.) 22 April 1980 see abstract.	1-10
Y	US, A, 3,929,137 (Gonser) 30 December 1975 see abstract.	1-10
Y	US, A, 5,078,743 (Mikalou et al.) 07 January 1992. see entire document.	60-68,80,90-92
Y	US, A, 4,230,119 (Blum) 28 October 1980 see entire document.	45,51-54,60-68,90-92
Y	US, A, 3,978,863 (Fettel et al.) 07 September 1976. see entire document.	31,43-45,51-54,60-68,80,90-92